IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

STANBIO LABORATORY, L.P.,	§	
A Texas Limited Partnership, and	§	
Plaintiff and Counter-Defendant	§	
	§	
v.	§	**Civil Action No. SA-03-CA-1080 (OG)**
	§	
HEMOCUE, INC. and	§	
HEMOCUE AB	§	
Defendants and Counterclaimants	§	
	§	
	§	
EKF-DIAGNOSTIC SALES, GmbH,	§	
a German Corporation,	§	
Plaintiff and Counter-Defendant	§	
	§	**Civil Action No. SA04CA807(OG)**
v.	§	**Consolidated with SA03CA1080(OG)**
	§	
HEMOCUE, INC. and	§	
HEMOCUE AB	§	
Defendants and Counterclaimants	§	

AMENDED COMPLAINT

Plaintiff, Stanbio Laboratory, L.P., complains of Defendants, HemoCue, Inc. and HemoCue AB, as follows:

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I.
PARTIES

1. Stanbio Laboratory, L.P. ("Stanbio") is a limited partnership organized under the laws of the State of Texas, with its principal place of business in Boerne, Texas, San Antonio Division of the Western District of Texas.

2. HemoCue, Inc. is a California corporation with its principal place of business in Lake Forest, California.

3. HemoCue AB is a Swedish corporation with its principal place of business in Ängelholm, Sweden.

II.
JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338 because it is a civil action arising under the laws of the United States, namely, 15 U.S.C.§§ 1, 2, 14, 1125, and 35 U.S.C. § 271.

5. This Court has personal jurisdiction over HemoCue, Inc. and HemoCue AB (collectively, "HemoCue") since they have sufficient contact with this State and, in particular, this Judicial District, and maintenance of the suit in this Judicial District does not offend traditional notions of fair play and substantial justice. Venue is proper in this District pursuant to 28 U.S.C. § 1391. A substantial part of Stanbio's claims arise in this Judicial District.

III.
FACTS

A. THE RELEVANT MARKETS

(a) POINT-OF-CARE TESTING FOR HEMOGLOBIN MARKET

6. Hemoglobin testing affects the health and safety of a substantial number of persons in the United States. HemoCue's brochure, A Small Test That Makes A Big Difference, Hemoglobin Testing in Primary Healthcare—A Faster Way To Make A Diagnosis, published at www.HemoCue.com/HemoCueint/pdf/anemia_brochure.pdf, accurately discusses in layman's terms anemia and the usefulness of diagnosing anemia by point-of-care testing for hemoglobin.

7. HemoCue publishes the following text concerning anemia and testing for hemoglobin to identify people at risk for anemia. The quoted text is truthful.

> Doctors have long been aware of the risk of anemia infants, teenage girls and women of childbearing age anemia is far more prevalent in elderly people and people with diabetes than previously known. A recent study demonstrates that anemia is a predictor of mortality and functional dependence in the elderly and that even mild levels of anemia are associated with poorer outcomes.
>
> Anemia in people with diabetes is a key indicator of disease, yet most diabetics are rarely tested for anemia and are unaware of the link between anemia and kidney disease. Testing for hemoglobin at the point of care quickly and easily identifies people at risk. (www.HemoCue.com.uk/sida_119.asp.)

8. HemoCue publishes the following text concerning anemia and testing for hemoglobin to identify people at risk for anemia. The quoted test is truthful.

> The hemoglobin level is the most-used parameter used screen blood donors for anemia. The HemoCue Hemoglobin systems can give the donor an exact hemoglobin value within sixty seconds. The photometer is small and portable which permits their use in mobile collection units.
> (www.HemoCue.com/hemocueint/sida_18.asp.)

9. Point-of-care testing ("POCT") is a term of art in the blood testing line of commerce which is generally defined as laboratory testing performed outside of the clinic laboratory. It can be performed at a walk-in clinic, at a patient's bedside or in a centralized area within a unit, such as an intensive care unit.

10. The following text from HemoCue's A Small Test That Makes a Big Difference, Hemoglobin Testing in Primary Healthcare—A Faster Way To Make A Diagnosis brochure on page 15 is a generally accurate definition of point-of-care testing for hemoglobin:

> Point-of-care testing (POCT) refers to tests carried out at or near the patient's bedside, or in primary care process, *e.g.*, during a doctor's visit . . . . It is important to emphasize that the POCT system used should not only provide fact results but also precise and accurate results, on which important clinical decisions may safely be based. The technique should be simple enough to allow it to be performed by personnel with a minimum of laboratory testing.

11. Point-of-care testing for hemoglobin typically uses whole blood collected using the finger stick method. While point-of care testing can use whole blood, venous, arterial, or core blood collected in a vacutainer, or heparin syringe, these latter methods are relatively inconsequential compared to collecting whole blood collected using the finger stick method in terms of the overall economic market for hemoglobin point-of-care testing.

12. The documents attached as **Exhibit A** to this Amended Complaint are accurate copies of documents created by HemoCue. The information stated in **Exhibit A** is truthful.

13. In **Exhibit A,** HemoCue states its "Business Idea" to be "We develop, produce and market in-vitro diagnostic products and services for the global professional point-of-care testing and home use markets." and shows "The Marketplace" for hemoglobin cuvettes and hemoglobin cuvette test meters to be the "professional decentralized testing" market. These are truthful statements.

14. Professional decentralized testing for hemoglobin in the United States typically uses whole blood collected using the finger stick method. While professional decentralized testing can use whole blood, venous, arterial, or core blood collected in a vacutainer, or heparin syringe, these latter methods are relatively inconsequential compared to collecting whole blood

collected using the finger stick method in terms of the overall economic market for hemoglobin professional decentralized testing.

15. HemoCue shows the professional decentralized testing market in **Exhibit A.2** as being comprised of "primary health care, POL's, occupational health, blood banks, diabetic clinics, public health, hospital POCT, and screening programs." This is a generally an accurate description of the market for professional decentralized testing for hemoglobin.

16. HemoCue further generally accurately defines the market segments of the preceding paragraph in **Exhibit A.4**.

17. In **Exhibit A.3**, HemoCue states the principal applications of its B-Hemoglobin system to be "screening, diagnosing, monitoring of anemia. Establishing O_2 – carrying capacity in the acutely ill patient." This is a truthful statement.

18. For practical purposes, the professional decentralized testing for hemoglobin market in the United States is generally equivalent to the point-of care testing for hemoglobin market in the United States. If HemoCue disputes this, please respond to each of the numbered averments of this pleading as needed where the definitional difference between "point-of-care testing" and "professional decentralized testing" changes the response to the averment.

(b) <u>POINT-OF-CARE TESTING FOR HEMOGLOBIN BY HEMOGLOBIN CUVETTES AND PHOTOMETER TEST METERS SUBMARKET</u>

19. The (1) copper sulfate, (2) hemocrit spinner, (3) Statsite M, (4) Multi-analyzers (5) Blood gas analyzer and (6) hemoglobin cuvette/photometric test meter, are each tests which test for hemoglobin or for an indication which is related to hemoglobin.

20. Hemoglobin cuvette/photometric test meters such as HemoCue's B-Hemoglobin test meter (1) use a disposable cuvette to acquire whole blood hemoglobin from a fingertip, mix the blood with chemicals within the cuvette to form a compound that can be measured

photometrically, (2) shine light through the sample, and (3) display a digital hemoglobin result. They are generally accurate, reliable, produce rapid results and are simple to use.

21. HemoCue's literature explains that the "Principal Applications" for hemoglobin cuvettes and hemoglobin cuvette test meters are "screening, diagnosing, and monitoring of anemia. Establishing the oxygen carrying caring capacity in the acutely ill patient." This HemoCue explanation is generally accurate.

22. The most typical use of HemoCue's hemoglobin cuvettes and hemoglobin cuvette test meters is for point-of-care testing determination of whole blood hemoglobin concentration.

23. Point-of-care testing for hemoglobin using HemoCue's hemoglobin cuvettes and hemoglobin test meters provides a hemoglobin count which is a more accurate hemoglobin count than the hemoglobin count produced by tests such as the (1) copper sulfate, (2) hemocrit spinner, (3) Multi-analyzers and (4) Blood gas analyzer tests.

24. None of (1) copper sulfate, (2) hemocrit spinner, (3) Multi-analyzers and (4) Blood gas analyzer tests are competitive with hemoglobin cuvette/photometer testing in the point-of-care testing for hemoglobin market.

25. HemoCue markets hemoglobin cuvettes and hemoglobin cuvette test meters, including B-Hemoglobin Photometer (photometry instrument) and B-Hemoglobin 201+, and a B-Hemoglobin cuvette.

26. On information and belief, the price HemoCue charges for the supplies used per test for hemoglobin cuvette/photometer testing exceed by at least fifty percent the price of supplies used per test for each of the (1) copper sulfate, (2) hemocrit spinner, (3) Multi-analyzers and (4) Blood gas analyzer tests.

27. On information and belief, HemoCue does not have data, analysis or reports indicating that HemoCue has lost five percent (5%) or more of its United States hemoglobin

cuvette sales due to HemoCue's customers electing to substitute any of the (1) copper sulfate, (2) hemocrit spinner, (3) Statsite M, (4) Multi-analyzers and (5) Blood gas analyzer tests for hemoglobin cuvette/ photometer testing in any of 2000, 2001, 2002, 2003 and 2004.

28. HemoCue advertises in its HemoCue User's Report No. 6 Critical Care that there are no alternatives to photometric hemoglobin test meters in the point-of-care testing market.

> "--Have you found any alternatives to HemoCue?
>
> --No, not at all. It would be impossible to use a spun hemocrit. It would need one person just to do that and it would be too costly for us. The small gadgets that some people use for glucose testing are too inaccurate and they are always lost when you need them. It would be impossible to have an on-site laboratory with all the equipment and maintenance needed. The convenient factor with HemoCue is very high.
>
> * * *
>
> --How do you look at the cost for using HemoCue?
>
> --The cost of using HemoCue is lower than purchasing a sophisticated machine that requires operators that are highly trained to run it. It gives us the same results. Anybody can quickly learn to run the HemoCue. It is so simple to use. You don't have to spend a lot of time training the staff on using it."

29. The above quoted text from HemoCue's advertising literature is a generally accurate statement of one of HemoCue's publicly available representations to potential point-of-care testing customers concerning whether alternatives exist to hemoglobin photometric test meters in the point of care testing market. The representation make in HemoCue's advertisement is a truthful representation.

30. On information and belief, HemoCue sometimes markets hemoglobin cuvette testing via a photometric test meter as being sufficiently different from alternative methods of testing for hemoglobin to warrant hemoglobin cuvette via a photometric test meter test systems

being viewed differently than alternative hemoglobin test systems by customers in the point-of-care hemoglobin testing market.

31. On information and belief, HemoCue sometimes markets hemoglobin cuvette testing via a photometric test meter as being sufficiently different from alternative methods of testing for hemoglobin to warrant a higher price per test for hemoglobin cuvette photometric test meter supplies than for alternative hemoglobin test systems in the point-of-care hemoglobin testing market.

32. Hemoglobin cuvette and photometer testing has been described as "the gold standard" for point-of-care testing determination of hemoglobin. HemoCue does not dispute this description.

33. On information and belief, HemoCue communicates to prospective customers for its hemoglobin cuvettes that, for point-of-care testing for hemoglobin at low complexity laboratories such as doctors' offices, and walk-in clinics, testing by hemoglobin cuvettes in photometric meters is more appropriate than (1) copper sulfate, (2) hemocrit spinner, (3) Multi-analyzers and (4) Blood gas analyzer test methods of taking a hemoglobin count.

34. On information and belief, HemoCue does not have data, analysis or reports indicating that HemoCue has lost substantial sales (more than one percent of HemoCue's total sales in the United States of HemoCue's point-of-care hemoglobin cuvettes) in the United States of HemoCue's hemoglobin cuvette tests due to HemoCue's customers substituting (1) copper sulfate, (2) hemocrit spinner, (3) Multi-analyzers and (4) Blood gas analyzer tests instead of hemoglobin cuvette tests for any of the years 2000, 2001, 2002, 2003, and 2004.

35. On information and belief, HemoCue's market data indicates that the average price per test paid to HemoCue for the cuvettes and other supplies needed to conduct point-of-care testing for hemoglobin using a HemoCue hemoglobin cuvette in the United States in 2003

was more than twice the average price per test paid to suppliers for the supplies needed to conduct a hemoglobin test or hemoglobin indicator test such as (1) copper sulfate, (2) hemocrit spinner, (3) Statsite M, (4) Multi-analyzers and (5) Blood gas analyzer tests.

36. HemoCue markets HemoCue's hemoglobin cuvette photometric test meter testing system in part as follows:

> "HemoCue's well-known technology is used daily by medical professionals all around the world and the systems are ideally suited for point of care hemoglobin testing in a primary health care setting. The benefits of the systems allow the physician to diagnose anemia and/or following therapy in a much more effective way.
>
> Key features:
>
> - Can be used by non-laboratory personnel after a brief training session
> - produces accurate lab quality results in less than a minute
> - Utilizes only 10 pl of capillary, venous or arterial blood
> - Precalibrated, portable photometers that require a minimum of maintenance
> - No calibration or instruction manipulation (between cuvette/reagent batches) needed
> - Automatically compensate for turbidity due to lipids or leucocytosis"

37. HemoCue represents to at least some of its customers that no test equipment, supplies, or method currently commercially available in the United States flood testing market provides all of these above benefits except point-of-care cuvette based photometric test meter hemoglobin testing.

38. HemoCue represents to at least some of its customers that while other methods of hemoglobin testing may be appropriate for high volume laboratory based testing or for testing where an accurate hemoglobin count is not important, there are no currently commercially available alternative types of test equipment, supplies, and methods for accurate point-of-care

hemoglobin testing compared to a point-of-care cuvette based photometric test meter hemoglobin testing system.

39. While other methods may be appropriate for high volume laboratory based testing or for testing where an accurate hemoglobin count is not important, there are no practical cost effective available alternative types of test equipment, supplies, and methods for accurate point-of-care hemoglobin testing compared to the group of point-of-care hemoglobin tests consisting of (1) cuvette based photometric test meter hemoglobin testing system, and (2) test strip hemoglobin testing system such as a Statsite M system.

40. On information and belief, in 2001, 2002 and 2003 the average price in the United States for a hemoglobin cuvette was more than the average price in the United States for a test strip used in test strip hemoglobin testing.

41. On information and belief, some blood testing organizations in the United States are considering switching their current hemoglobin testing system to hemoglobin cuvette based photometric test meter testing due to the advantages of the hemoglobin cuvette based photometric test meter method over other systems.

42. Hemoglobin test strip meters are a point of care test method for hemoglobin.

43. The per-test cost to purchase a hemoglobin cuvette and supplies to conduct a hemoglobin cuvette photometric hemoglobin test is more than the cost to purchase a hemoglobin test strip and supplies to conduct a hemoglobin test strip hemoglobin test.

44. Point-of-care test purchasers of hemoglobin test products in the United States typically either use hemoglobin cuvette technology or hemoglobin test strip technology.

45. HemoCue markets its point-of-care hemoglobin cuvette-based tests as being superior to point-of-care hemoglobin test strip tests.

46. Despite the lower cost of the hemoglobin test strips relative to hemoglobin cuvettes, more point-of-care blood testers in the United States typically purchase hemoglobin cuvettes rather than hemoglobin test strips.

47. On information and belief, of hemoglobin tests conducted in the United States which use either hemoglobin test strip tests or hemoglobin cuvettes combined, less than ten percent of the tests were test strip tests.

(c) HEMOCUE'S INSTALLED BASE SUBMARKET

48. Several businesses, clinics, offices, non-profits, governmental entities, etc. (collectively "organizations") in the United States use HemoCue's hemoglobin cuvettes and hemoglobin cuvette photometric test meters for the purpose of testing hemoglobin.

49. On information and belief, since January 1, 2002, most of the organizations in the United States which used hemoglobin cuvettes/hemoglobin photometric test meters for their point of care hemoglobin testing have maintained or expanded their use of hemoglobin test cuvettes for their point-of-care hemoglobin testing.

50. On information and belief, since January 1, 2003, less than ten percent of the organizations in the United States which used hemoglobin photometric test meters for point-of-care hemoglobin testing have replaced their hemoglobin photometric test meters with other hemoglobin test technologies.

51. Organizations in the United States which currently use hemoglobin cuvette and photometric test meter technology to measure hemoglobin would incur a switching cost to change from testing hemoglobin via their current hemoglobin cuvettes and photometric test meter technology to another method of measuring hemoglobin.

52. Organizations in the United States which currently use HemoCue's hemoglobin cuvettes and HemoCue cuvette test meters to measure hemoglobin would incur a switching cost

to change from their current HemoCue hemoglobin cuvettes and HemoCue photometric test meters to another method of measuring hemoglobin.

53. On information and belief, for some organizations in the United States which currently use hemoglobin cuvette and photometric test meters for point-of-care hemoglobin testing, the cost of switching from hemoglobin cuvettes/photometric test meters to a different method of point-of-care hemoglobin testing would exceed the benefit of switching.

54. Testing for hemoglobin in the United States using HemoCue's hemoglobin cuvettes with HemoCue's test meters comprises a "waived" test under Clinical Laboratory Improvement amendments ("CLIA"). It is advantageous for a test to be waived under CLIA.

55. A test which is waived may be conducted in a low complexity laboratory. A test which is not waived may not be conducted in a low complexity laboratory. It is more expensive to establish, equip, and staff a high complexity laboratory than a low complexity laboratory for hemoglobin testing.

56. Currently, only HemoCue's hemoglobin cuvettes have CLIA waived status for use in HemoCue's hemoglobin test meters in a low complexity laboratory.

57. Organizations in the United States who currently use hemoglobin cuvettes/photometric test meters for their point-of-care hemoglobin testing comprise a relevant consuming market.

58. United States blood testing organizations which currently use hemoglobin cuvettes/photometric test meters to test for hemoglobin comprise a "hemoglobin cuvette/photometric test meter installed base" or "installed base."

59. On information and belief, in 2003, HemoCue test meters were used by more than 90% of the United States hemoglobin cuvette/photometric test meter installed base.

60. On information and belief, in 2004, HemoCue test meters were used by more than 90% of the United States hemoglobin cuvette/photometric test meter installed base.

61. On information and belief, currently, HemoCue test meters are used by more than 90% of the United States hemoglobin cuvette/photometric test meter installed base.

62. On information and belief, in 2003, HemoCue sold more than 90% of the hemoglobin cuvettes used by hemoglobin cuvette/photometric test meter installed base test meters in the United States.

63. On information and belief, in 2004, HemoCue sold more than 90% of the hemoglobin cuvettes used by hemoglobin cuvette/photometric test meter installed base test meters in the United States.

64. On information and belief, currently, HemoCue sells more than 90% of the hemoglobin cuvettes used by hemoglobin cuvette/photometric test meter installed base test meters in the United States.

65. On information and belief, in 2002, no business except HemoCue sold new hemoglobin cuvette photometric test meters in the United States.

66. On information and belief, in 2003, no business except HemoCue sold new hemoglobin photometric cuvette test meters in the United States.

67. On information and belief, in 2004, only Stanbio sold new hemoglobin cuvette photometric test meters in the United States in competition with HemoCue.

68. On information and belief, currently, only Stanbio sells new hemoglobin cuvette test meters in the United States in competition with HemoCue.

69. On information and belief, in 2003, no business sold hemoglobin cuvettes which could be lawfully used in HemoCue's hemoglobin cuvette photometric test meters, except HemoCue, with the disputed possible exception of Stanbio.

70. On information and belief, in 2004, no business sold hemoglobin cuvettes which could be lawfully used in HemoCue's hemoglobin cuvette photometric test meters except HemoCue, with the disputed possible exception of Stanbio.

71. On information and belief, currently, no business sells hemoglobin cuvettes which can be lawfully used in HemoCue's hemoglobin cuvette test meters in the United States, with the disputed exception of Stanbio.

B. HEMOCUE'S MONOPOLY POWER

(a) HEMOCUE'S PATENT MONOPOLIES

72. On information and belief, from about 1982 through about 1996, HemoCue was the only supplier of hemoglobin test cuvettes and photometric test meters used for photometric point-of-care testing for hemoglobin in the United States. On information and belief, this was due in part to one or more patents owned by HemoCue which excluded competition for many years. In particular, HemoCue's U.S. Patent No. 4,088,448 (the '448 patent) issued May 9, 1978, excluded competition in the hemoglobin cuvette market within the scope of the '448 patent's claims.

73. However, the monopoly patents give is for a limited duration, i.e., 20 years. When the '488 patent expired in 1996, competitors became free to make hemoglobin cuvettes disclosed in the '448 patent. Additionally, competitors became free to make hemoglobin cuvettes which were anticipated or made obvious by the cuvettes disclosed in the '448 patent. This is the consideration the public receives in exchange for granting the patentee a monopoly for a limited term.

74. Prior to the 1996 expiration of the '448 patent, HemoCue filed a patent application on a cuvette inner channel and other cuvette improvements, which application led to

U.S. Patent No. 5,674,457 (the '457 patent), and European Patent No. 821,784 (the European '784 patent). The '457 patent is the only patent asserted by HemoCue against Stanbio.

75. HemoCue contends that HemoCue's '457 patent prevents competitors from selling hemoglobin test cuvettes in the United States which infringe the '457 patent's claims.

76. HemoCue's '457 patent will not expire until April 2015.

77. HemoCue's website states in large, italicized, boxed, set apart, quoted type, "*OUR SYSTEMS ARE BASED ON PATENTED CUVETTE TECHNOLOGY*"

(b) HEMOCUE DOMINATES THE GLOBAL MARKET FOR POINT-OF-CARE HEMOGLOBIN CUVETTES AND TEST METERS

78. HemoCue AB of Sweden markets its point-of-care test hemoglobin cuvette and test meters internationally (www.HemoCue.com/hemocueint/sida_29.asp).

79. A January 2005 press release by HemoCue states in part, "Today, HemoCue is a global leader in diagnostic point-of-care testing." (Published in Advance/Laboratory). HemoCue's website advertises that "since the introduction, we have installed almost 200,000 B-Hemoglobin and B-Glucose instruments globally." HemoCue's quoted statements are truthful.

80. On information and belief, in each of the years 2000, 2001, 2002, 2003, and 2004, HemoCue sold more hemoglobin cuvettes used for point-of-care testing of hemoglobin in the world than all other suppliers in the world of hemoglobin cuvettes used for point-of-care testing of hemoglobin combined.

81. HemoCue advertises that every three seconds, a HemoCue cuvette is used somewhere in the world and that HemoCue has sold almost one billion cuvettes. These are truthful statements.

82. On information and belief, HemoCue currently sells more hemoglobin cuvettes for use in test meters in the world and in the United States for point-of-care testing for hemoglobin than any other supplier of hemoglobin cuvettes.

83. On information and belief, HemoCue currently sells more photometric test meters in the world and in the United States for point-of-care testing for hemoglobin than any other supplier of photometric test meters.

(c) HEMOCUE DOMINATES THE UNITED STATES MARKET FOR POINT-OF-CARE HEMOGLOBIN TEST CUVETTES AND TEST METERS

84. HemoCue AB primarily markets its point-of-care test hemoglobin cuvettes and test meters via separate county economic units and business entities staffed with in-county personnel. HemoCue, Inc. is a wholly-owned subsidiary of HemoCue AB. HemoCue, Inc. is headquartered in California. HemoCue, Inc. has no employees located outside of the United States. (www.HemoCue.US).

85. Effective January 7, 2004, the statement "HemoCue, Inc. sells its products in the United States through a combination of third-party distributors and an internal sales force of 15 sales representatives who are employed by HemoCue, Inc." was accurate. (Declaration of Charles Neff, National Sales Manager for HemoCue, Inc., January 7, 2004).

86. On information and belief, HemoCue's sales in the United States from 1982 through 2002 are generally accurately shown on **Exhibit A.5**.

87. On information and belief, HemoCue, Inc.'s sales of HemoCue hemoglobin cuvettes and hemoglobin cuvette test meters are primarily focused on the United States geographic market.

88. On information and belief, in each of the years 2000, 2001, 2002, 2003, and 2004, HemoCue sold more hemoglobin cuvettes in the United States than all other suppliers of hemoglobin cuvettes combined in that year.

89. On information and belief, in each of the years 2000, 2001, 2002, 2003, and 2004, HemoCue sold more hemoglobin photometric test meters in the United States than all other suppliers of hemoglobin photometric test meters combined in that year.

90. On information and belief, in each of the years, 2000, 2001, 2002, 2003, and 2004, HemoCue sold more than 90% of the hemoglobin test cuvettes and photometric test meters for hemoglobin cuvettes sold in the United States in that year.

91. From 2003 until the current time, there are no sellers of hemoglobin test cuvettes and photometric test meters for hemoglobin cuvettes in the United States except for HemoCue and Stanbio (and their distributors).

92. On information and belief, in each of the years 2000, 2001, 2002, 2003, and 2004, HemoCue sold more point-of-care hemoglobin tests (point-of-care hemoglobin tests consisting of both hemoglobin cuvettes and hemoglobin test strips) than all other suppliers of point-of-care hemoglobin tests combined in that year.

93. On information and belief, in each of the years 2000, 2001, 2002, and 2003, HemoCue sold more hemoglobin cuvettes into the United States point-of-care testing market than all other suppliers of hemoglobin cuvettes to that market combined in that year.

94. On information and belief, in each of the years 1994, 1995, 1996, 1997, 1998, 1999, 2000, 2001, 2002, and 2003, HemoCue sold more than 90% of the photometric test meters for hemoglobin cuvettes in the United States in that year.

(d) HEMOCUE HAS MONOPOLY POWER IN THE MARKET FOR CUVETTES USED FOR THE HEMOGLOBIN POINT-OF-CARE TESTING MARKET IN THE UNITED STATES

95. The relevant geographic market for hemoglobin test cuvettes and hemoglobin cuvette test meters sold in the United States is the United States.

96. On information and belief, HemoCue sold more than 70% of the hemoglobin tests within the group consisting of point-of-care testing hemoglobin cuvettes and point-of-care testing hemoglobin test strips sold in the United States in each of 2000, 2001, 2002, 2003, and 2004.

97. On information and belief, HemoCue sold more than 90% of the point-of-care testing hemoglobin test cuvettes sold in the United States in each of 2000, 2001, 2002, 2003, and 2004.

98. On information and belief, HemoCue sold more than 95% of the point-of-care testing hemoglobin test cuvettes sold in the United States in each of 2000, 2001, 2002, 2003, and 2004.

99. On information and belief, in 2003, HemoCue's average sales price for its hemoglobin cuvettes in the United States was more than 20% higher than HemoCue's average sales price for its point of care hemoglobin cuvettes sold outside of the United States.

100. On information and belief, in 2004, HemoCue's average sales price for its hemoglobin cuvettes in the United States was more than 20% higher than HemoCue's average sales price for its point of care hemoglobin cuvettes sold outside of the United States.

101. On information and belief, in 2003, HemoCue's average sales price for its point of care hemoglobin cuvettes in the United States was more than 30% higher than the average sales price for its point of care hemoglobin cuvettes sold by HemoCue outside of the United States.

102. On information and belief, in 2004, HemoCue's average sales price for its hemoglobin cuvettes in the United States was more than 30% higher than the average sales price for its point of care hemoglobin cuvettes sold by HemoCue outside of the United States.

103. On information and belief, in 2002, HemoCue's average gross profit (defined as revenue less cost of goods) for its point of care hemoglobin cuvettes in the United States expressed as a percentage relative to HemoCue's cost of goods for its point of care hemoglobin cuvettes was more than 100%. Restated, HemoCue's average gross profit for its hemoglobin cuvettes exceeded HemoCue's cost of goods for the same in the United States.

104. On information and belief, in each of 2001, 2002, and 2003, HemoCue's average net profit (defined as revenue less all costs of obtaining that revenue) for its point of care test hemoglobin cuvettes in the United States was more than 100%.

105. Hemoglobin test cuvettes sold into the United States point-of-care testing market are hereby defined for the purpose of this pleading to comprise a relevant product and geographic market collectively referred to as a "First Relevant Market".

106. On information and belief, in each of 2000, 2001, 2002, and 2003, HemoCue's market share in the First Relevant Market exceeded 90 percent.

107. On information and belief, HemoCue's current market share in the First Relevant Market exceeds 80 percent.

108. On information and belief, HemoCue's current market share in the First Relevant Market exceeds 90 percent

109. On information and belief, HemoCue has market power, a dangerous probability of acquiring monopoly power, and monopoly power in the First Relevant Market.

(e) HEMOCUE HAS MONOPOLY POWER IN THE MARKET FOR PHOTOMETRIC TEST METERS IN THE UNITED STATES

110. The relevant geographic market for point of care hemoglobin photometric cuvette test meters sold in the United States is the United States.

111. On information and belief, HemoCue sold more than 90% of the point of care hemoglobin photometric test meters sold in the United States in each of 2000, 2001, 2002, 2003, and 2004.

112. On information and belief, HemoCue sold more than 95% of the photometric point of care hemoglobin photometric test meters sold in the United States in each of 2000, 2001, 2002, 2003, and 2004.

113. Point of care hemoglobin photometric test meters sold into the United States point-of-care testing market are hereby defined for the purpose of this pleading to comprise a relevant product and geographic market collectively referred to as a "Second Relevant Market".

114. On information and belief, in each of 2000, 2001, 2002, and 2003, HemoCue's market share in the Second Relevant Market exceeded 90 percent.

115. On information and belief, HemoCue's current market share in the Second Relevant Market exceeds 80 percent.

116. On information and belief, HemoCue's current market share in the Second Relevant Market exceeds 90 percent

117. On information and belief, HemoCue has market power, a dangerous probability of acquiring monopoly power, and monopoly power in the Second Relevant Market.

(f) HEMOCUE HAS MONOPOLY POWER IN THE MARKET FOR CUVETTES USED IN INSTALLED POINT-OF-CARE PHOTOMETRIC HEMOGLOBIN TEST METERS IN THE UNITED STATES

118. The relevant geographic market for hemoglobin test cuvettes sold for use in installed point-of-care photometric hemoglobin test meters in the United States is the United States.

119. On information and belief, point-of-care photometric hemoglobin test meters are currently only sold in the United States by HemoCue and by Stanbio.

120. The relevant consumer market for hemoglobin test cuvettes for use in installed point-of-care photometric hemoglobin test meters in the United States is organizations which currently own HemoCue or Stanbio point-of-care hemoglobin photometric test meters.

121. The relevant product market for hemoglobin test cuvettes for use in HemoCue's hemoglobin photometric test meters in the United States is hemoglobin test cuvettes which may be lawfully used within HemoCue's point-of-care hemoglobin photometric test meters in the United States.

122. On information and belief, HemoCue sold at least 95% of the hemoglobin test cuvettes used within installed point-of-care hemoglobin photometric test meters in the United States in each of the years 2000, 2001, 2002 and 2003.

123. On information and belief, HemoCue sold more than 95% of the hemoglobin test cuvettes sold in the United States for use in installed point-of-care hemoglobin photometric test meters in the United States in 2004.

124. On information and belief, HemoCue sold more than 95% of the hemoglobin test cuvettes sold in the United States for use in installed point-of-care hemoglobin photometric test meters in the United States in 2005 to date.

125. On information and belief, in each of the years 2000, 2001, 2002 and 2003, HemoCue's average sales price for its hemoglobin cuvettes in the United States for use in installed point-of-care hemoglobin photometric test meters was more than 20% higher than HemoCue's average sales price for its hemoglobin cuvettes sold outside of the United States for use in installed point-of-care hemoglobin photometric test meters.

126. On information and belief, in 2002, HemoCue's average gross profit (defined as revenue less cost of goods) for its point-of-care hemoglobin cuvettes in the United States expressed as a percentage relative to HemoCue's cost of goods for HemoCue's point of care hemoglobin test cuvettes was more than 100%. Restated, HemoCue's average gross profit for its hemoglobin cuvettes exceeded HemoCue's cost of goods for the same in the United States.

127. On information and belief, in each of 2001, 2002, and 2003, HemoCue's average net profit (defined as revenue less all costs of obtaining that revenue) for its point-of-care test hemoglobin cuvettes in the United States was more than 100%.

128. Hemoglobin test cuvettes sold into the United States point-of-care testing market for use in installed point-of-care hemoglobin photometric test meters in the United States are hereby defined for the purpose of this pleading to comprise a relevant product and geographic market, referred to as a Third Relevant Market.

129. On information and belief, in each of 2000, 2001, 2002, and 2003, HemoCue's market share in the Third Relevant Market exceeded 90 percent.

130. On information and belief, HemoCue's current market share in the Third Relevant Market exceeds 80 percent.

131. On information and belief, HemoCue's current market share in the Third Relevant Market exceeds 90 percent

132. On information and belief, HemoCue has market power, a dangerous probability of acquiring monopoly power, and monopoly power in the Third Relevant Market.

(g) HEMOCUE HAS MONOPOLY POWER IN THE MARKET FOR CUVETTES USED IN HEMOCUE'S HEMOGLOBIN TEST METERS IN THE UNITED STATES

133. HemoCue asserts that only HemoCue's hemoglobin test cuvettes may be lawfully used within HemoCue's hemoglobin photometric test meters in the United States.

134. Current owners of HemoCue hemoglobin photometric test meters in the United States are locked into purchasing HemoCue hemoglobin cuvettes for use their HemoCue hemoglobin test meters unless they are willing to replace their current HemoCue hemoglobin photometric test meters.

135. HemoCue asserts that all non-HemoCue currently commercially available hemoglobin cuvettes in the United States which are useful within HemoCue's hemoglobin test meters infringe HemoCue's '457 patent.

136. HemoCue asserts that hemoglobin test cuvettes currently provided by any suppliers other than HemoCue in the United States are less reliable in HemoCue's hemoglobin photometric test meters than HemoCue's hemoglobin cuvettes.

137. HemoCue asserts that no currently commercial available hemoglobin cuvettes other than HemoCue's hemoglobin cuvettes may be lawfully used within HemoCue's hemoglobin test meters in the United States.

138. HemoCue's hemoglobin cuvettes and hemoglobin test meters comprise a "cluster market," *i.e.* a cluster of products that itself is the object of customer demand. As the sole supplier of HemoCue cuvettes and HemoCue hemoglobin photometric test meters to this cluster market, HemoCue has monopoly power and/or relevant power in this market.

C. STANBIO'S ENTRY INTO HEMOCUE'S HEMOGLOBIN POINT-OF-CARE TESTING MARKET

139. Stanbio sells clinical diagnostic products. Stanbio began business in Hallettsville, Texas in 1958, relocated to San Antonio in 1964, and relocated again to its present address in Boerne, Texas in 2001.

140. Stanbio entered a distribution agreement with EKF-Diagnostic GmbH ("EKF"), a German manufacturer of diagnostic products including hemoglobin test cuvettes and test meters, to import and sell EKF's hemoglobin test cuvette in the United States.

141. Stanbio was informed and reasonably believed EKF's test cuvette was lawfully based on HemoCue's prior art unpatented hemoglobin cuvettes and HemoCue's expired '448 patent.

142. EKF's hemoglobin cuvette appears to the naked eye to be substantially the same as at least some of HemoCue's hemoglobin cuvettes which HemoCue marketed prior to April 26, 1994.

143. Stanbio markets EKF's cuvette in the United States as the H2 HEMOPOINT cuvette.

144. HemoCue's B-HEMOGLOBIN cuvette and Stanbio's H2 HEMOPOINT cuvette compete for sales in the United States.

145. HemoCue's B-HEMOGLOBIN test meter and Stanbio's HEMOPOINT test meter compete for sales in the United States.

146. HemoCue asserts that the H2 HEMOPOINT hemoglobin cuvettes sold by EKF to Stanbio and offered for sale by Stanbio in the United States infringe the '457 patent, that Stanbio is marketing Stanbio's cuvettes unlawfully, have threatened litigation against Stanbio thereon and have sued Stanbio for the same.

147. HemoCue asserts that Stanbio's sale of hemoglobin test cuvettes which are intended to be used within HemoCue's B-Hemoglobin test meters is unlawful regardless of whether or not Stanbio's cuvettes infringe the '457 patent and that Stanbio is otherwise unlawfully marketing the H2 HEMOPOINT cuvette.

148. Stanbio has a reasonable apprehension of being sued by HemoCue for infringement of the '457 patent and the above listed grounds.

D. HEMOCUE'S '457 PATENT IS INVALID.

(a) HEMOCUE'S UNDISCLOSED PRE-APRIL 26, 1994, CUVETTES WERE MATERIAL PRIOR ART AGAINST THE INVENTION CLAIMED IN THE '457 APPLICATION

149. The patent application leading to the '457 patent was filed April 26, 1995.

150. April 25, 1994, one year prior to the above filing date, is the "bar date" for the '457 patent. Cuvettes which were known to the public, sold, offered for sale, or otherwise in the public domain prior to April 26, 1994, are referred to as "prior art" with respect to the '457 patent. The invention claimed in the '457 patent must be novel and non-obvious in light of the prior art to be patentable. 35 U.S.C. §§ 102, 103.

151. Prior to April 26, 1994, HemoCue sold hemoglobin test cuvettes.

152. Prior to April 26, 1994 (and for a period thereafter), HemoCue's hemoglobin cuvettes were protected from competition from identical cuvettes sold by others by HemoCue's '448 patent, which was filed on or about September 16, 1976.

153. HemoCue's hemoglobin cuvettes underwent structural changes between the cuvettes shown in the '448 patent filed September 16, 1976, and April 25, 1994.

154. HemoCue's United States Design Patent No. 337,388, filed July 13, 1993 (the '388 patent"), (the front page only attached as **Exhibit B**) shows a cuvette which uses capillary action to pull blood into the cuvette.

155. The '388 patent discloses an integral capillary microcuvette comprising a body member having a curved outer peripheral edge, the body member being provided with a cavity that communicates with the outer peripheral edge of the body member, the cavity being defined

by two opposing inner surfaces of the body member, a portion of the cavity defining a measuring zone within the body member.

156. The '388 patent additionally shows an outer peripheral edge of the body member being provided with a sample inlet through which a sample is drawn into the body member.

157. Jan Lilja, one of the listed inventors of the '457 patent, is additionally an inventor of United States Patent No. 4,654,197 ("the '197 patent"). The filing date of the '197 patent predates the filing date of the '457 patent by more than one year.

158. The '197 patent states in part:

> Body member having at least one cavity defined by surrounding walls, into which cavity a sample is permitted to enter by capillary force through an inlet communicating said cavity with the exterior of said body member . . . (Column 1, lines 35-40)
>
> When the same is drawn into the cavity 12, air is pressed out through the slit 15 . . . The area 17 indicates a suitable measuring zone. (Column 4, lines 59-63)

159. The '197 patent discloses a cuvette having a measuring zone, a space between the measuring zone and an end of an inner peripheral zone, and capillary action drawing the sample in and pressing air out of the cuvette.

160. Jan Lilja, one of the listed inventors of the '457 patent, is additionally an inventor of United States Patent No. 5,286,454 ("the '454 patent"). The filing date of the '454 patent predates the filing date of the '457 patent by more than one year.

161. The '454 patent states in part:

> When using the cuvette according to FIGS. 1 and 2, the first cavity 12 is filled with a liquid sample which in the illustrated embodiment is drawn into the cavity by capillary action through the inlet 13. The liquid sample mixes with reagent or the like provided in the cavity 12, and the mixture can then be analysed, e.g., in a photometer. (Column 3, line 60 to column 4, line 2.)

162. Prior to April 26, 1994, HemoCue sold glucose test cuvettes which use capillary action to pull blood into the cuvette.

163. HemoCue's U.S. Federal Trademark Registration No. 2,629,645, issued October 8, 2002, (**Exhibit C**) shows a cuvette. This trademark registration states that the logo shown therein was first used in commerce in 1982. On information and belief, cuvettes having the design shown in this trademark registration were sold prior to April 26, 1994. The cuvette shown in this registration has a space located between the cuvette's measuring zone and the end of the cuvette's inner peripheral zone.

164. The space shown extends along the entire inner peripheral zone of the cuvette.

165. HemoCue sold hemoglobin cuvettes as shown in **Exhibit D** prior to April 26, 1994. HemoCue published **Exhibit D** prior to April 26, 1994.

166. The hemoglobin cuvette that HemoCue sold and published as shown in **Exhibit D** had a space located between its measuring zone and the end of the cuvette's inner peripheral zone.

167. Prior to April 26, 1994, hemoglobin and glucose cuvettes from HemoCue or others were publicly known or published (These are referred to as "prior art cuvettes").

168. Prior to April 26, 1994, HemoCue sold or published at least some cuvettes which were substantially similar to the cuvette drawing shown in '457 Figure 1. No reference is made in this averment to any inner dimensions or shape of channel 10 in the physical cuvette itself, but only to Figure 1, the drawing itself, which does not show any inner dimensions or shape of channel 10. For example, the drawing of Figure 10 of the '457 patent is substantially the same as the figures of **Exhibits C** or **D**.

169. Prior to April 26, 1994, at least some of HemoCue's prior art cuvettes had a structure which was more similar to Figure 1 of the '457 patent (Figure 1 not showing any inner

dimensions or shape of channel 10) than to the structure of the cuvettes shown in the Figures of the '448 patent.

170. On information and belief, at least one of HemoCue's pre-April 26, 1994, prior art cuvettes had a measuring zone which did not extend to the end of the cuvette's inner peripheral zone.

171. On information and belief, at least one of HemoCue's pre-April 26, 1994, prior art cuvettes contained a structure which may be fairly described as "the outer peripheral edge of the body member being provided with a sample inlet though which a sample is drawn into the body member."

172. BioTest offered evidence in a BioTest v. HemoCue Opposition to the European '784 patent which evidence BioTest argued showed that HemoCue sold cuvettes with at least some of the European '784 patent's claimed invented features prior to April 26, 1994.

173. On information and belief, BioTest's BioTest v. HemoCue European Opposition Exhibits D-4 through D-11 show at least one pre-April 26, 1994, prior art cuvette.

174. On information and belief, at least some of HemoCue's pre-April 26, 1994, prior art cuvettes had the structure shown in BioTest's Exhibit D-9.

175. The HemoCue label shown in BioTest v. HemoCue Opposition Exhibit D-9 shows a date of "1991 10 03." On information and belief, the cuvette shown in D-9, or a cuvette substantially similar to the cuvette shown in D-9, was sold by HemoCue prior to April 26, 1994.

176. HemoCue did not inform the '457 patent's patent examiner that, prior to April 26, 1994, HemoCue published and sold cuvettes which were an integral capillary microcuvette comprising a body member having a curved outer peripheral edge, the body member being provided with a cavity that communicates with the outer peripheral edge of the body member, the cavity being defined by two opposing inner surfaces of the body member, a portion of the

cavity defining a measuring zone within the body member which used capillary action to pull blood into the cuvette.

(b) HEMOCUE MISREPRESENTED THE '457'S APPLICATION'S COMPARISON TEST TO THE PATENT EXAMINER.

177. HemoCue represented to the Patent Examiner in the application leading to the '457 patent ("The Application") that "cuvettes according to the present invention were compared with cuvettes **according to** U.S. Patent No. 4,088,448 . . . 100 cuvettes **according to** U.S. Patent No. 4,088,448 available from HemoCue AB, Sweden and 100 cuvettes according to the present invention were filled with the above reagent . . . " (Column 3, lines 14-26, Emphasis added).

178. On information and belief, the reference HemoCue cuvettes actually used in The Application's test (Column 3, lines 14-26) ("cuvettes **according to** U.S. Patent No. 4,088,448") were not identical to the cuvettes shown in the '448 patent.

179. On information and belief, the prior art reference HemoCue cuvettes actually used in the comparison test of The Application (Column 3, lines 14-26) had a structure that was substantially similar to the cuvette shown in either or both **Exhibits C** and **D**.

180. On information and belief, the prior art reference HemoCue cuvettes actually used in the comparison test of The Application (Column 3, lines 14-26) had a structure that was substantially similar to the cuvette shown in BioTest Opposition Exhibit D-9.

181. On information and belief, the prior art reference HemoCue cuvettes actually used in the comparison test of The Application (Column 3, lines 14-26) had a structure that was substantially similar to the cuvette shown in BioTest Opposition Exhibit D-11.

182. On information and belief, the prior art reference HemoCue cuvettes used in the comparison test of The Application (Column 3, lines 14-26) had a structure that was similar to

the drawing shown in Figure 1 of the '457 patent (Figure 1 of the '457 patent not showing the inner dimensions or shape of channel 10).

183. HemoCue represented to the Patent Examiner that the reference cuvettes of The Application were "cuvettes according to U.S. Patent No. 4,088,448 available from HemoCue AB, Sweden." (Column 3, lines 14-26.)

(c) HEMOCUE MISREPRESENTED THE STATE OF THE PRIOR ART TO THE PATENT EXAMINER

184. The '448 patent which HemoCue represented to the Patent Examiner as representing the prior art did not disclose cuvettes having a "cavity having an inner peripheral zone at which is located a channel, the channel extending along the entire inner peripheral zone of the cavity."

185. On information and belief, at least some of HemoCue's pre-April 26, 1994 prior art cuvettes had a "cavity having an inner peripheral zone at which is located a channel, the channel extending along the entire inner peripheral zone of the cavity." HemoCue did not disclose this fact to the '457 patent's Patent Examiner.

186. HemoCue did not inform the Patent Examiner of any differences between (1) cuvettes according to the figures of '448 and (2) HemoCue's pre-April 26, 1994 prior art cuvettes which were most similar to the cuvettes of the '457 patent.

187. HemoCue did not disclose the '454 patent, the '197 patent, or the '388 patent (**Exhibit B**) to the '457 patent's Patent Examiner.

188. U.S. Federal Trademark Registration No. 2,629,645 (**Exhibit C**) shows a cuvette having a "cavity having an inner peripheral zone at which is located a channel, the channel extending along the entire inner peripheral zone of the cavity."

189. HemoCue did not disclose prior art cuvettes having the structure shown in U.S. Federal Trademark Registration No. 2,629,645 to the '457 patent's Patent Examiner.

190. HemoCue did not disclose its cuvettes shown in **Exhibit D** to the Patent Examiner.

191. HemoCue did not disclose the cuvettes shown in BioTest Exhibits D-4 through D-11 to the Patent Examiner.

192. HemoCue did not disclose all of prior art in HemoCue possession at the time to the '457 patent's Patent Examiner which prior art showed some of the features claimed in the '457 patent application.

(d) HEMOCUE MISREPRESENTED THE NOVELTY OF THE '457 APPLICATION'S CHANNEL 10 TO THE PATENT EXAMINER

193. The cuvettes shown in BioTest opposition Exhibits D-4 through D-11 have a "cavity having an inner peripheral zone at which is located a channel, the channel extending along the entire inner peripheral zone of the cavity . . . ."

194. The cuvettes shown in BioTest opposition Exhibits D-4 through D-11 have all of the structure of the invention claimed in Claim 1 of the '457 patent, except that , *arguendo,* the channel of BioTest Exhibits D-4 through D-11, which channel is located approximately where '457's channel 10 is located, may or may not have decreased in width toward the outer edge.

195. The cuvettes shown in BioTest opposition Exhibits D-4 through D-11 have all of the structure of the invention claimed in Claim 1 of the '457 patent, except that, *arguendo,* the Exhibits D-4 through D-11 cuvettes did not have a channel similar '457's channel 10.

196. In HemoCue's prosecution of the '457 patent application, HemoCue's December 6, 1996 Amendment asserted structural differences between the *Fielding* and *Hillman* prior art references on the one hand and the '457 patent application's claimed invention structure

on the other hand, to argue that the invention claimed in the '457 patent application was patentable.

197. The *Hillman* and *Fielding* prior art references show channels which decrease toward in width toward an outer edge and exhibit capillary action.

198. The '457 patent likely would not have issued if the Patent Examiner had combined the cuvette shown in BioTest opposition Exhibits D-4 through D-11 with the *Fielding* and *Hillman* prior art references. This is because the invention of claim 1 of the '457 patent would be unpatentable in light of (a) the Exhibits D-4 through D-11 cuvette, which had all of the structure of the invention claimed in Claim 1 of the '457 patent, except, *arguendo,* that channel 10 of the Exhibits D-4 through D-11 cuvette may not decrease toward the edge of the inner peripheral zone, combined with (b) the channels of *Hillman* and *Fielding*, which channels decrease in width progressing toward an outer edge and which channels exhibit capillary action.

199. If the Patent Examiner had combined HemoCue's prior art cuvette shown in **Exhibits B, C** and **D** with the *Fielding* and *Hillman* prior art references, the '457 patent likely would not have issued.

200. HemoCue misrepresented the patentability of the '457 patent's invention cuvette in HemoCue's December 6, 1996 Response by distinguishing the invention cuvette from the *Hillman* and *Fielding* references without informing the Patent Examiner of HemoCue's prior art cuvettes.

(e) HEMOCUE MISREPRESENTED THE NOVELTY OF OTHER STRUCTURES IN THE '457 APPLICATION TO THE PATENT EXAMINER

201. The Patent Examiner's March 3, 1997 Notice of Allowance stated as "an examiner's statement of reasons for allowance":

> The following is an examiner's statement of reasons for allowance: The prior art of record fails to teach or suggest an integral capillary micro-cuvette comprising a combination of a body member having an outer peripheral edge, the body member being provided with a cavity that communicates with the outer peripheral edge of the body member, the cavity being defined by two opposing inner surfaces of the body member, a portion of the cavity being defined by two opposing inner surfaces of the body member, a portion of the cavity defining a measuring zone within the body member, the cavity having an inner peripheral zone at which is located a channel, the channel extending along the entire inner peripheral zone of the cavity, the channel being sized relative to measuring zone such that the channel has a higher capillary force than the measuring zone to prevent air bubbles from becoming trapped in the measuring zone, the outer peripheral edge of the body member being provided with a sample inlet though which a sample is drawn into the body member, the sample inlet being in communication with the channel and the channel being in communication with the measuring zone.

202. The Patent Examiner's March 3, 1997 Notice of Allowance shows that allowance of Claim 1 of the '457 patent was dependent on HemoCue adding additional structure into Claim 1. This additional structure included, without limitation, at least:

> (1) "the channel being a size relative to the measuring zone such that the channel has a higher capillary force in the measuring zone to prevent air bubbles from becoming trapped in the measuring zone,"
>
> (2) "the cavity having an inner peripheral zone at which is located a channel," and
>
> (3) "the channel extending along the entire inner peripheral zone of the cavity."

203. At lease some of HemoCue's pre-April 26, 1994, prior art cuvettes had a "cavity having an inner peripheral zone at which is located a channel" structure.

204. At least some of HemoCue's pre-April 26, 1994, prior art cuvettes had a "channel extending along the entire inner peripheral zone of the cavity" structure.

205. The Patent Examiner having indicated that patentability was dependent in part on these "novel" structures in his Notice of Allowance, and HemoCue's undisclosed prior art

cuvettes having these structures, HemoCue's failure to inform the Patent Examiner of HemoCue's prior art cuvettes comprises withholding material art from the Patent Examiner.

206. Prior to April 26, 1994, HemoCue was using "a dry reagent in a predetermined amount" in HemoCue's prior art cuvettes.

207. Claim 3 of the '457 patent states in part "wherein said cavity includes a dry reagent in a predetermined amount."

208. HemoCue did not disclose to the Patent Examiner that prior to April 26, 1994 HemoCue was using "a dry reagent in a predetermined amount" in its prior art hemoglobin cuvettes.

209. On information and belief, HemoCue's prior problems with bubbles in its cuvettes were caused in part by the prior dry reagent used in its hemoglobin cuvette, and the problems were reduced by changing reagents. HemoCue did not inform the Patent Examiner of this.

(f) THE '457 PATENT FAILS U.S. PATENT LAW'S BEST MODE, ENABLEMENT, WRITTEN DESCRIPTION, DEFINITENESS, AND OPERABILITY REQUIREMENTS.

210. 35 USC § 112 states in part:

> "The specification shall contain **[1]** a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is mostly nearly connected, to make and use the same, and **[2]** shall set forth the best mode contemplated by the inventor of carrying out his invention. **[3]** The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." (bracketed numbers added)

These are each separate conditions of patentability. Any claim of the '457 patent which fails any of these three parts of 35 U.S.C. § 112 is invalid.

211. HemoCue possessed at least 100 of the '457 patent's invention cuvettes when it filed the '457 patent application on April 26, 1995 ('457 patent, Column 3, Line 23).

212. HemoCue did not include the exact measurements of channel 10 of '457 patent's 100 invention cuvettes in the '457 patent application.

213. The '457 patent's most precise numerical disclosure of channel 10's internal dimensions is "the channel 10 preferably has a width between 10 micron and 2 mm." (Column 2, Lines 48-49).

214. When HemoCue filed the application leading to the '457 patent, HemoCue knew the internal dimensions of channel 10 of the '457 patent's 100 invention cuvettes to a greater degree of detail than HemoCue disclosed in the '457 patent.

215. The '457 patent application states "in a preferred embodiment of measuring hemoglobin, the [measuring zone 4] distance should be between 0.05 and 0.15 mm." (Column 2, Lines 36-38).

216. In actuality, since prior to the '457 patent's April 26, 1994 bar date, HemoCue's commercially sold hemoglobin cuvettes had a standard preferred measuring zone distance of 0.15 mm. HemoCue's photometric test meters for its hemoglobin cuvettes were preset for cuvettes having an approximate 0.15 mm measuring zone since the 1980. HemoCue did not disclose this fact to the patent examiner.

217. The above width ranges disclosed in the '457 patent for measuring zone 4 (0.05 to 0.15 mm) and channel 10 overlap.

218. On information and belief, the '457 patent did not teach persons with ordinary skill in the art, on the '457 patent's filing date of April 26, 1995, how to make a cuvette having a channel 10 which provides a higher capillary force sufficient to prevent air bubbles from getting

trapped in the measuring zone as claimed in the '457 patent's Claim 1 without undue experimentation.

219. The dimensions stated in the '457 patent for measuring zone 4 and channel 10 do not meet United States patent law's (1) best mode (2) enablement or (3) description requirements.

220. Claim 1's "the channel being a size relative to the measuring zone such that the channel has a higher capillary force than the measuring zone to prevent air bubbles from becoming trapped in the measuring zone" is indefinite. *Motion International Co. v. Cardinal Chemical Co.*, 5 F.3d 1464 (Fed. Cir. 1993).

221. Claim 1 and claims depending from Claim 1 are invalid due to being indefinite.

222. Claim 1's "the channel being a size relative to the measuring zone such that the channel has a higher capillary force than the measuring zone to prevent air bubbles from becoming trapped in the measuring zone" is inoperable. Claim 1 and claims depending from Claim 1 are invalid due to being inoperable.

(g) HEMOCUE BREACHED ITS DUTY OF CANDOR TO THE PATENT EXAMINER

223. Litigants in the United States are typically not required to offer evidence against their own position, the American system of jurisprudence looking to the adversary to submit such evidence. However, an applicant applying for a grant of a patent monopoly prosecutes his patent application *ex parte*. Because of the absence of an adversary offering adverse evidence, patent applicants owe a duty of candor and good faith to the patent examiner. *Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, Inc.*, 394 F.3d 1348 (Fed. Cir. 2005) ("Patent applicants owe a 'duty of candor and good faith' to the PTO. 37 C.F.R. § 1.56(a) (2004) [citation omitted]. A breach of this duty may constitute inequitable conduct, which can

arise from a failure to disclose information material to patentability, coupled with an intent to deceive or mislead the PTO."

224. HemoCue's representations to the Patent Office in HemoCue's '457 patent application and HemoCue's Responses to Office Actions contained material omissions and/or mischaracterizations of the prior art in violation of HemoCue's duty of candor.

225. HemoCue's characterization of the state of the art references considered by the Patent Examiner, including, without limitation, the *Fielding* and *Hillman* references was misleading because, contrary to HemoCue's representations to the Patent Examiner, HemoCue's own prior art glucose or hemoglobin cuvettes contained features of the claimed invention not shown in the prior art references considered by the Examiner.

226. The state of the art references considered by the Patent Examiner, including, without limitation, the *Fielding* and *Hillman* references, were criticized by HemoCue. However, HemoCue's own prior art glucose or hemoglobin cuvettes had features which were more material to patentability than the *Fielding* and *Hillman* references.

227. HemoCue's failure to disclose to the Patent Office that HemoCue had prior art cuvettes and had patents on cuvettes which contained at least some claimed features of the '457 patent invention cuvette and which prior art was not known to the Patent Examiner was material to the examination of the application that matured into the '457 patent.

228. On information and belief, a neutral observer having possession of the '457 patent's prosecution history and the above undisclosed prior art, including the BioTest v. HemoCue European patent appeal evidence, U.S. Trademark Registration No. 2,269,645, the '197 patent, the '484 patent, the '388 patent, and HemoCue's prior art cuvettes would reasonably conclude that the '457 patent is almost certain to be declared invalid and/or unenforceable.

229. Alternatively, if the undisclosed prior art discussed above would have been insufficient to invalidate the '457 patent, it was material to the examination of the application that matured into the '457 patent.

230. "In evaluating materiality, we have consistently referred to the definition provided in 37 C.F.R. § 1.56, by which the PTO has promulgated the duty of disclosure . . . As defined in the current version of the rule, information is material to patentability when:

> [I]t is not cumulative to information already of record or being made of record in the application, and
>
> (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
>
> (2) It refutes, or is inconsistent with, a position the applicant takes in:
>
> (i) Opposing an argument of unpatentability relied on by the Office, or
>
> (ii) Asserting an argument of patentability.

37 C.F.R. § 1.56(b) (2004) (emphasis added by the Court); *Bruno*, *supra*, at 1352.)

231. On information and belief, HemoCue's failure to disclose this information was motivated by an intent to mislead and/or deceive the Patent Office in violation of the duty of disclosure, candor, and good faith.

232. On information and belief, HemoCue acquired the '457 patent through inequitable conduct.

233. HemoCue is estopped in view of the prior art and/or by virtue of cancellations, amendments, representations, and concessions made to the United States Patent Office, during the pendency of the application for the '457 patent, from construing any claim of that patent to be infringed by Stanbio.

(h) HEMOCUE IS HIDING THE BALL

234. Stanbio was informed and believes, on information and belief, that Stanbio's accused cuvettes are within the lawful scope of the prior art, particularly including HemoCue's pre-April 26, 1995, prior art cuvettes.

235. Stanbio cannot verify that Stanbio's accused cuvettes are or are not within the lawful scope of HemoCue's pre-April 26, 1995 prior art cuvettes without Stanbio having at least some information concerning HemoCue's prior art cuvettes.

236. Stanbio has asked HemoCue to deliver to Stanbio some of HemoCue's pre-April 26, 1994 cuvettes. Correspondence of January 10, 2005 from Stanbio's counsel to HemoCue's counsel is attached as **Exhibit E**.

237. Stanbio's First of Requests for Production to Defendant HemoCue requested production of HemoCue's prior art cuvettes and other information concerning the structure of HemoCue's prior art cuvettes such as drawings of them.

238. As of May 2, 2005, the date of this pleading, HemoCue has not delivered or produced to Stanbio any of HemoCue's prior art cuvettes or any drawings of HemoCue's prior art cuvettes.

239. As of May 2, 2005, the date of this pleading, HemoCue has not enabled Stanbio to compare Stanbio's accused cuvette with HemoCue's pre-April 26, 1995 prior art cuvettes or drawings of HemoCue's pre-April 26, 1994 cuvettes so Stanbio can verify that Stanbio's accused cuvettes are or are not within the lawful scope of HemoCue's pre-April 26, 1994 prior art cuvettes.

240. On information and belief, HemoCue possesses or can obtain either some of HemoCue's pre-April 26, 1994 prior art cuvettes or possesses or can obtain drawings or other information concerning the structure of HemoCue's pre-April 26, 1994 prior art cuvettes. HemoCue has not provided the same to Stanbio as of the date of this pleading.

241. HemoCue's conduct of hiding the ball estops, bars, or limits HemoCue from recovery of patent infringement damages and/or precludes Stanbio's infringement, if any, from being willful infringement, at least until HemoCue provides this requested information.

E. HEMOCUE HAS MISUSED ITS MONOPOLY POWER.

(a) HEMOCUE WILLFULLY ACQUIRED MONOPOLY POWER

242. After HemoCue's '448 patent expired, BioTest Medizintechnik GmbH ("BioTest"), a German company, marketed hemoglobin cuvettes which BioTest asserted were based on the teachings of the expired '448 patent. BioTest filed a European Patent Office ("EPO") opposition to invalidate the European '784 patent (the European patent corresponding to the U.S. '457 patent). An initial EPO panel invalidated European '784 Patent. Thereafter, HemoCue appealed the EPO panel decision and purchased BioTest. BioTest (now owned by HemoCue) did not oppose HemoCue's appeal. Pursuant to the unopposed appeal, the EPO reinstated European '784 patent on or about June 11, 2003.

243. After HemoCue acquired BioTest, HemoCue was the only supplier of hemoglobin cuvettes used for point-of-care photometric testing for hemoglobin in the United States market.

(b) THE '457 PATENT GIVES HEMOCUE MARKET POWER IN THE HEMOGLOBIN POINT-OF-CARE TESTING MARKET

244. The '457 patent gives HemoCue the power to exclude competitors from selling hemoglobin cuvettes in the United States which infringe the '457 patent's claims.

245. HemoCue has asserted the '457 patent to exclude competitors, including Stanbio, from selling hemoglobin cuvettes which HemoCue argues infringe the claims of the '457 patent.

246. HemoCue has used the '457 patent to help HemoCue sell more hemoglobin test cuvettes and hemoglobin cuvette test meters in the United States than HemoCue would have sold without the '457 patent.

247. HemoCue has communicated to Stanbio's customers and prospective customers that the '457 patent will, through this instant suit, likely prevent Stanbio from supplying Stanbio's hemoglobin cuvettes.

248. HemoCue has communicated to Stanbio's customers and prospective customers that HemoCue will seek a preliminary injunction against Stanbio supplying Stanbio's hemoglobin cuvettes.

249. HemoCue has communicated to Stanbio's customers and prospective customers that HemoCue will seek an early preliminary injunction against Stanbio supplying Stanbio's hemoglobin cuvettes and that a preliminary injunction against Stanbio is likely to be granted.

250. The '457 patent aids HemoCue's acquisition and maintenance of (1) market power, and (2) monopoly power, in the market for point of care hemoglobin test cuvettes in the United States.

251. HemoCue's communications to customers and prospective customers concerning how HemoCue will use the '457 patent to prevent Stanbio from supplying Stanbio's hemoglobin cuvettes have adversely affected Stanbio's sale of point of care hemoglobin cuvettes and test meters.

252. HemoCue has used the '457 patent to deter or exclude competitors from selling hemoglobin test cuvettes in the United States or lessen competition from competitors for the sale of hemoglobin test cuvettes in the United States.

253. The '457 patent aids HemoCue's acquisition and maintenance of (1) market power, and (2) monopoly power, in the hemoglobin test cuvette market in the United States.

(c) HEMOCUE HAS BUNDLED SALES OF ITS HEMOGLOBIN CUVETTES AND TEST METERS AND ENTERED LONG-TERM EXCLUSIVE DISTRIBUTION AGREEMENTS

254. On information and belief, HemoCue did not provide a substantial number of its HemoCue hemoglobin cuvette test meters at no cost to purchasers of HemoCue hemoglobin test cuvettes in the United States in the years 2000, 2001, 2002 and 2003.

255. On information and belief, HemoCue did not provide a substantial number of its HemoCue test meters in the United States to purchasers of HemoCue hemoglobin test cuvettes at a reduced price contingent upon the purchaser also committing to purchase a large quantity of HemoCue's hemoglobin cuvettes in the years 2000, 2001, 2002 and 2003.

256. On information and belief, since January 1, 2004, HemoCue has, on some occasions, offered to sell and has sold HemoCue hemoglobin cuvette test meters and HemoCue hemoglobin cuvettes to purchasers in the United States as part of a single sales agreement.

257. On information and belief, since January 1, 2004, HemoCue has offered bundled sales of its hemoglobin test cuvettes and hemoglobin cuvette test meters and has made bundled sales of its hemoglobin test cuvettes and hemoglobin cuvette test meters.

258. On information and belief, since January 1, 2004, HemoCue has on at least some occasions offered HemoCue hemoglobin cuvette test meters to purchasers of HemoCue hemoglobin test cuvettes for free or at a reduced price if the purchaser agreed to a large purchase of HemoCue's hemoglobin test cuvettes and has made sales on that basis.

259. On information and belief, since Stanbio has begun offering its hemoglobin cuvettes into the United States, HemoCue has offered to provide HemoCue hemoglobin test meters for free or at a reduced price, on at least some occasions, to purchasers in the United States conditioned on the purchaser agreeing to purchase a quantity of HemoCue hemoglobin cuvettes which exceeds the purchaser's expected need for cuvettes during the next year.

260. On information and belief, since Stanbio has begun offering its hemoglobin cuvettes into the United States, HemoCue has offered to provide and has actually provided

HemoCue hemoglobin test meters for free or at a reduced price, on at least some occasions, to purchasers in the United States conditioned on the purchaser agreeing to purchase HemoCue hemoglobin cuvettes over a period of time exceeding one year.

(d) HEMOCUE HAS ENGAGED IN UNLAWFUL PRICE DISCRIMINATION

261. On information and belief, since Stanbio has begun offering hemoglobin test meters for sale in the United States HemoCue has, on at least some occasions, offered to sell and sold its hemoglobin test meters in the United States for less than the price HemoCue sells its equivalent hemoglobin test meters for in Sweden and less than HemoCue's cost of manufacturing and delivering the test meters..

262. On information and belief, since Stanbio has begun offering hemoglobin test meters for sale in the United States, HemoCue has, on at least some occasions, offered to sell and sold its hemoglobin test meters in the United States for less than the price HemoCue sells its equivalent hemoglobin test meters for in Europe and less than HemoCue's cost of manufacturing and delivering the test meters.

263. On information and belief, since Stanbio has begun offering hemoglobin test meters for sale in the United States, HemoCue has, on at least some occasions, offered to sell and sold its hemoglobin test meters in the United States for less than the price at which Stanbio sells test meters and for less than Stanbio's cost of purchasing Stanbio's test meters.

264. On information and belief, since Stanbio has begun offering hemoglobin test cuvettes for sale in the United States, HemoCue has, on at least some occasions, offered to sell and sold its hemoglobin test cuvettes in the United States for less than Stanbio's list price for Stanbio's hemoglobin test cuvettes.

265. On information and belief, HemoCue sells its hemoglobin cuvettes and hemoglobin test meters in the United States across state lines in competition with Stanbio's sale of hemoglobin cuvettes and its hemoglobin test meters in the United States across state lines.

266. On information and belief, since Stanbio began offering to sell its hemoglobin cuvettes and its hemoglobin test meters in the United States, HemoCue has offered to sell and has sold HemoCue's hemoglobin cuvettes and HemoCue's hemoglobin test meters to purchasers at different prices and upon different terms.

267. On information and belief, since Stanbio has begun offering to sell hemoglobin cuvettes and test meters in the United States, HemoCue has, on at least some occasions, offered to sell and sold HemoCue hemoglobin cuvettes for less than the average variable cost for such HemoCue hemoglobin cuvettes and for less than HemoCue's list prices and terms.

268. On information and belief, since Stanbio has begun offering to sell hemoglobin cuvettes and test meters in the United States, HemoCue has, on at least some occasions, offered to sell and sold HemoCue hemoglobin test meters for less than the average variable cost for such HemoCue hemoglobin test meters, and for less than HemoCue's list prices and terms..

269. On information and belief, HemoCue's sale of hemoglobin cuvettes and hemoglobin test meters has been upon prices less than Stanbio's list prices for equivalent hemoglobin cuvettes and hemoglobin test meters and at terms more favorable to the purchaser than Stanbio's equivalent hemoglobin cuvettes and hemoglobin test meters.

270. Currently, hemoglobin test cuvette customers at high complexity laboratories who use HemoCue's B-Hemoglobin Photometer may choose to use either HemoCue's B-Hemoglobin cuvette or Stanbio's HemoPoint cuvette within the photometer.

271. HemoCue has introduced a new hemoglobin test meter, the HemoCue Hemoglobin Haemoglobin 201 Plus, which will not accept Stanbio's cuvette or the current cuvette of any other supplier of cuvettes.

272. When a customer replaces HemoCue's B-Hemoglobin Photometer with a HemoCue hemoglobin 201 Plus test meter, a portion of the market for the sale of hemoglobin test cuvettes is foreclosed to Stanbio and other suppliers of hemoglobin test cuvettes, if any.

273. Stanbio's HemoPoint cuvette will not work within HemoCue's hemoglobin 201 Plus test meter.

274. Currently, no businesses supply hemoglobin test cuvettes in the United States which work within HemoCue's hemoglobin 201 Plus test meter.

275. On information and belief, an effect of HemoCue asserting the '457 patent against Stanbio, is to delay Stanbio's and other businesses' entry into the hemoglobin test cuvette market in the United States while HemoCue converts HemoCue test cuvette customers who currently have HemoCue's B-Hemoglobin photometer over to HemoCue's haemoglobin 201 Plus test meter. This is because, while Stanbio's hemoglobin test cuvette will work within HemoCue's B-hemoglobin photometer, Stanbio's hemoglobin test cuvette will not work within HemoCue's haemoglobin 201 Plus test meter.

276. On information and belief, HemoCue's sale of hemoglobin cuvettes and hemoglobin test meters at different prices and terms to different customers has been done with an intent to sell HemoCue's hemoglobin cuvettes and hemoglobin test meters to customers who might otherwise have purchased hemoglobin cuvettes and hemoglobin test meters from Stanbio.

(e) HEMOCUE HAS ENGAGED IN UNFAIR COMPETITION

277. On information and belief, HemoCue's sales personnel have, on at least some occasions since Stanbio has begun offering to sell hemoglobin cuvettes and test meters in competition with HemoCue, told customers or prospective customers of Stanbio (1) Stanbio's hemoglobin cuvettes infringe a HemoCue patent, or (2) Stanbio's cuvettes do not have proper governmental authorization to be used with HemoCue test meters in high complexity laboratories, or (3) current governmental authorization to use Stanbio cuvettes with HemoCue's

test meters in high complexity laboratories may be withdrawn, or (4) Stanbio's cuvettes are inferior to HemoCue's cuvettes, or (5) Stanbio may not be able to lawfully continue to supply Stanbio's hemoglobin cuvettes.

278. On information and belief, HemoCue has made statements to Stanbio's customers and prospective customers that are likely to deceive Stanbio's customers and prospective customers as to the lawfulness, quality, and usefulness of Stanbio's hemoglobin cuvettes. On information and belief, HemoCue intended these statements to influence these entities to either avoid or cease doing business with Stanbio.

279. HemoCue has communicated to customers and prospective customers of cuvettes for use in the HemoCue B-Hemoglobin Photometer that only "HemoCue cuvettes purchased from HemoCue" should be used in the HemoCue B-Hemoglobin Photometer, or words that effect.

280. Stanbio's hemoglobin cuvettes currently have federal governmental approval to be used in HemoCue's B-Hemoglobin meter in high complexity laboratories.

281. Stanbio's hemoglobin cuvettes are equally useful in HemoCue's B-Hemoglobin Photometer as are HemoCue's B-Hemoglobin cuvettes in high complexity laboratories.

282. On information and belief, HemoCue has no evidence that Stanbio's cuvettes are not equally useful in HemoCue B-Hemoglobin Photometer as are HemoCue's B-Hemoglobin cuvettes in high complexity laboratories.

283. On information and belief, purchasers and potential purchasers of hemoglobin cuvettes have been dissuaded from purchasing Stanbio cuvettes from Stanbio because of HemoCue's communications to customers and prospective customers that only "HemoCue cuvettes purchased from HemoCue" should be used with HemoCue's Photometer, or words to that effect.

284. On information and belief, (1) this lawsuit, (2) the '457 patent, (3) HemoCue's communications to Stanbio's customers and prospective customers concerning Stanbio's ability to continue to lawfully deliver hemoglobin cuvettes, (4) HemoCue's communications to Stanbio's customers and prospective customers concerning whether Stanbio's cuvettes infringe the '457 patent, (5) HemoCue's communications to Stanbio's customers and prospective customers concerning whether or not Stanbio's cuvettes are as useful in HemoCue's test meter, (6) HemoCue's communications to Stanbio's customers and prospective customers concerning whether or not Stanbio's cuvettes are as useful in HemoCue's B-Hemoglobin Photometer as HemoCue's B-Hemoglobin cuvettes, and (7) HemoCue's other complained-of acts have impeded Stanbio's sales of Stanbio's hemoglobin test meters and cuvettes.

285. On information and belief, HemoCue is using one or more of the complained-of acts to impede Stanbio's entry into the United States hemoglobin test cuvette market and United States hemoglobin cuvette test meter market while HemoCue attempts to transition much of the United States' point-of-care hemoglobin test market from HemoCue's B-Hemoglobin Photometer to HemoCue's haemoglobin 201 Plus test meter.

286. On information and belief, HemoCue has specifically intended its above described conduct to lessen Stanbio's sales of Stanbio's cuvettes and test meters and to increase or maintain HemoCue's sales and to acquire or maintain HemoCue monopoly power.

(f) ADVERSE EFFECTS OF HEMOCUE'S ACTS

287. On information and belief, HemoCue's complained-of acts have adversely affected competition in the market for point-of-care testing hemoglobin cuvettes and point-of-care hemoglobin test meters in the United States market.

288. On information and belief, HemoCue has extended the market power and monopoly power afforded it in the hemoglobin cuvette market by the '457 patent into the hemoglobin cuvette test meter market in the United States.

289. On information and belief, HemoCue's '457 patent and the threat of litigation asserting the '457 patent has provided and provides HemoCue with the power to exclude competition in the First Relevant Market and the power to control prices in the First Relevant Market.

290. On information and belief, HemoCue's '457 patent and the threat of litigation asserting the '457 patent has provided and provides HemoCue with the power to leverage its market power in the First Relevant Market into the power to adversely affect and exclude competition and control prices in the Second Relevant Market.

291. On information and belief, HemoCue has used the '457 patent and claims concerning the '457 patent to adversely affect and exclude competitors from the Second Relevant market.

292. On information and belief, HemoCue's actions have adversely affected competition in the market to supply hemoglobin test cuvettes and test meters, the point-of-care testing market including WIC clinics, blood banks, hospitals and the persons who use them, the pregnant women, young children, donors of blood and users of blood. The public's health and welfare has been adversely affected.

293. On information and belief, as a direct and proximate result of HemoCue's anti-competitive conduct, Stanbio has been injured in its business and property and has suffered and continues to suffer irreparable harm to its customer relationships and business reputation.

294. On information and belief, HemoCue's above actions have inflicted upon Stanbio "injury of the type the antitrust laws were intending to prevent and that flows from that which makes [HemoCue's] acts unlawful." HemoCue is attempting to eliminate horizontal competition presented by Stanbio, which harms competition and, ultimately, consumers. Specifically, HemoCue's complained of acts have caused injury to Stanbio and its business and property, and

deprives customers, such as WIC clinics, hospitals and blood banks and ultimately to pregnant mothers, young children, persons donating blood of a competitive market for hemoglobin test cuvettes and test meters.

295. On information and belief, HemoCue's above described acts have been committed knowingly and willfully and with reckless disregard for the rights of Stanbio and will continue unless enjoined by this Court.

296. Due to HemoCue's above described acts, Stanbio has been required to incur costs and attorney's fees.

IV.
CAUSES OF ACTION

COUNT ONE
DECLARATORY JUDGMENT OF NON-INFRINGEMENT

297. Stanbio does not infringe and has not infringed any claim of the '457 patent, either literally or under the Doctrine of Equivalents. Because there exists a real and justiciable controversy regarding infringement of the '457 patent, this Court should make a declaration that Stanbio does not infringe the '457 patent.

COUNT TWO
DECLARATORY JUDGMENT OF INVALIDITY

298. The '457 patent is invalid and void for failure to comply with the requirements of Title 35, United States Code, including but not limited to Sections 102, 103, and/or 112. Because there exists a real and justiciable controversy regarding the validity of the '457 patent, this Court should make a declaration that the '457 patent is invalid.

COUNT THREE
DECLARATORY JUDGMENT OF NO UNFAIR COMPETITION BY STANBIO

299. Stanbio's cuvettes are lawful products and are being lawfully marketed. Stanbio has not engaged in any unfair business practices or unfair competition or breached the Lanham Act. Because there exists a real and justiciable controversy, this Court should make a declaration

that Stanbio's cuvettes are lawful products which Stanbio is lawfully marketing and Stanbio has not engaged in any unfair business practices or unfair competition or breached the Lanham Act.

300. Specifically, without limitation, Stanbio requests a declaratory judgment that its cuvettes may be lawfully used in HemoCue's test meters in high complexity laboratories.

COUNT FOUR
DECLARATORY JUDGMENT THAT THE '457 PATENT IS UNENFORCEABLE

301. During the prosecution of the '457 patent application, HemoCue failed to comply with its duty of candor to the Patent Examiner.

302. The '457 patent is unenforceable because of inequitable conduct by HemoCue, including, without limitation, failing to disclose known material prior art and as further alleged herein.

COUNT FIVE
WALKER PROCESS CLAIM

303. HemoCue is liable to Stanbio for a *Walker Proc*ess violation. *Walker Process v. Food Machinery and Chemical Corp.*, 382 U.S. 172 (1965), *Nobel Pharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059 (Fed. Cir. 1998).

304. Specifically, without limitation, (1) the '457 patent is invalid or unenforceable; (2) HemoCue made one or more material misrepresentations or omissions to the Patent Examiner during prosecution of the application leading to the '457 patent by (a) misrepresenting to the Patent Examiner that the test set out in the application "proving" the usefulness of the invention was made against the structure shown in U.S. Patent No. 4,088,448 when it was not, (b) misrepresenting in the application and in the patent prosecution process that no closer prior art existed than the prior art discussed in the patent application and in the prosecution process; and (c) the other defects in the '457 application and prosecution alleged herein; (3) the misrepresentation or omissions were made in bad faith because HemoCue had possession of closer prior art and/or material facts at the time it made the above misrepresentations and

omissions to the Patent Examiner; (4) HemoCue is attempting to enforce the '457 patent having knowledge that the '457 patent is invalid or unenforceable; and (5) HemoCue has monopoly power or an ability to obtain monopoly power and is using the '457 patent for the purpose of maintaining or obtaining monopoly power.

305. HemoCue is continuing to assert the '457 patent against Stanbio in spite of these matters being pointed out to HemoCue by Stanbio.

COUNT SIX
SHAM LITIGATION – *AB INITIO*

306. HemoCue's assertion of the '457 patent against Stanbio comprises unlawful sham litigation.

307. Specifically, without limitation, (1) HemoCue is asserting a patent, the '457 patent, against Stanbio, (2) HemoCue's claim is "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits," and (3) the baseless lawsuit conceals an attempt to interfere directly with the business relationships of a competitor . . . through the "use [of] the governmental process – as opposed to the outcome of that process – as an anti-competitive weapon." *Professional Real Estate Investors, Inc. v. Columbia Pictures Industrial, Inc.,* 508 U.S. 49, 60-61 (1993) (internal citations omitted).

308. Stanbio's packages are prominently labeled "HEMOPOINT® H2 Microcuvettes" on the top line in approximately 11 point type next to a large red Stanbio logo and the words "Stanbio Laboratory."

309. The bottom of the label is comprised of red band which states in white relief, "Stanbio Laboratory. 1261 North Main, Boerne. Tex. USA 78006."

310. Beneath the upper "HEMOPOINT® H2 Microcuvette" heading is the informative statement, "For use with the HEMOPOINT® H2 Meter and HEMOCUE® H-Hemoglobin Meter" in six-point type. This informative statement is a truthful statement. This is further

explained at the bottom of the label: "HemoCue® is a registered trademark of HemoCue AG, Amgelholm, Sweden." This informative statement is a truthful statement.

311. HemoCue contends that Stanbio may not lawfully market a hemoglobin cuvette which fits within HemoCue's B-Hemoglobin test meter.

312. HemoCue's claim that the above label comprises trademark infringement and that Stanbio may not lawfully market a hemoglobin cuvette which fits within HemoCue's B-Hemoglobin test meter are unlawful sham claims.

COUNT SEVEN
SHAM LITIGATION – IN PROCESS

313. Alternatively, although HemoCue initially asserted the '457 patent and Lanham Act claim in good faith (1) HemoCue has subsequently obtained knowledge that the '457 patent is invalid and the Lanham Act claim is not meritorious; and (2) HemoCue has continued to knowingly seek to enforce the invalid '457 patent and assert its unmeritorious Lanham Act claim. Further, (3) HemoCue has monopoly power or an ability to obtain monopoly power and is using the '457 patent and Lanham Act claim for the purpose of maintaining or obtaining monopoly power. *Hangards, Inc. v. Ethicon, Inc.*, 743 F.2d 1282 (9th Cir. 1984).

COUNT EIGHT
REFUSAL TO LICENSE

314. HemoCue has unlawfully refused to license the '457 patent to Stanbio. HemoCue (1) possesses monopoly power in the United States markets for POCT hemoglobin cuvettes and point of care hemoglobin cuvette test meters; (2) HemoCue has refused to license the '457 patent to actual competitor and potential competitor Stanbio in the market of point-of-care testing hemoglobin cuvettes; (3) HemoCue has refused to license the '457 patent to Stanbio with the specific intent to (a) establish or maintain a monopoly in the point-of-care testing hemoglobin cuvette market when HemoCue knows its '457 is invalid or unenforceable and (b) established or maintain HemoCue's monopoly in the market for hemoglobin test meters.

COUNT NINE
UNLAWFUL TYING

315. Hemoglobin test cuvettes and hemoglobin cuvette test meters are separate products.

316. HemoCue has unlawfully tied sales of its hemoglobin cuvette test meters to its hemoglobin cuvettes.

317. Specifically, without limitation, (1) the tying arrangement has an actual anti-competitive effect by reducing competition in the tied product; and (2) there is no valid business justification for the tie. (Rule of Reason)

318. Specifically, (1) HemoCue has market power in the tying product, *i.e.* hemoglobin cuvette test meters; (2) HemoCue has coerced others to purchase the tied product, i.e., hemoglobin cuvettes meters from HemoCue, by conditioning sale or favorable terms of the tying product to the buyer's agreement to buy the tied product from HemoCue. HemoCue's market power is shown by its percentage of sales of hemoglobin test meters. (Per Se)

319. HemoCue has unlawfully tied sales of its hemoglobin test cuvettes to its hemoglobin cuvette test meters.

320. Specifically, without limitation, (1) the tying arrangement has an actual anti-competitive effect by reducing competition in the tied product; and (2) there is no valid business justification for the tie. (Rule of Reason)

321. Specifically, (1) HemoCue has market power in the tying product, *i.e.* hemoglobin cuvette test meters; (2) HemoCue has coerced others to purchase the tied product, i.e., hemoglobin cuvettes meters from HemoCue by conditioning sale or favorable terms of the tying product to the buyer's agreement to buy the tied product from HemoCue. HemoCue's market power is shown by its percentage of sales of hemoglobin test meters. (Per Se)

COUNT TEN
UNLAWFUL EXCLUSIVE DEALING

322. HemoCue has entered into unlawful exclusive dealing agreements concerning its hemoglobin cuvettes and test meters.

323. HemoCue has monopoly power or market power in the United States market for point-of care testing hemoglobin cuvettes.

324. HemoCue has entered into arrangements with buyers of hemoglobin cuvettes which explicitly or practically are exclusive agreements, *i.e.*, the buyer will obtain all or substantially all of the buyers' requirements for point of care hemoglobin cuvettes from HemoCue.

325. HemoCue has monopoly power or market power in the United States market for point-of care testing hemoglobin cuvette test meters.

326. HemoCue has entered into arrangements with buyers of hemoglobin cuvette test meters which are exclusive agreements, *i.e.*, the buyer will obtain all or substantially all of the buyers' requirements for point of care hemoglobin cuvette test meters from HemoCue.

327. HemoCue has entered into arrangements with buyers of hemoglobin cuvettes and hemoglobin cuvette test meters, in which, explicitly or practically, the cuvettes and meters are being bundled or sold as a package. Further, these agreements, explicitly or practically, are exclusive agreements.

328. These agreements have the effect of reducing competition in the United States in (1) the point of care hemoglobin test cuvette market, (2) the point of care hemoglobin cuvette test meter market, (3) the point of care hemoglobin cuvette and test meter market, and point of care hemoglobin testing market.

COUNT ELEVEN
MONOPOLIZATION AND ATTEMPTED MONOPOLIZATION

329. HemoCue has attempted to monopolize the United States (1) (1) the point of care hemoglobin test cuvette market, (2) the point of care hemoglobin cuvette test meter market, (3) the point of care hemoglobin cuvette and test meter market, and point of care hemoglobin testing market, and the United States point-of-care test hemoglobin cuvette test meter market (Second Relevant Market).

330. Specifically, without limitation, HemoCue has (1) a specific intent to control prices or destroy competition in these markets; (2) used predatory or anti-competitive conduct to accomplish the monopolization; (3) a dangerous probability of success; and (4) caused antitrust injury to Stanbio.

331. HemoCue's '457 patent has enabled HemoCue to obtain prices for its hemoglobin cuvettes and hemoglobin cuvette test meters which are higher than the prices HemoCue could obtain without the '457 patent.

332. HemoCue has used the '457 patent to monopolize and to attempt to monopolize these markets.

333. Specifically, without limitation, HemoCue has (1) a specific intent to use the '457 patent to control prices or destroy competition in these markets; (2) used the '457 patent to accomplish or attempt to accomplish or attempt to accomplish the monopolization; (3) a dangerous probability of success; and (4) caused antitrust injury to Stanbio.

334. HemoCue brought this objectively baseless action with the intent to monopolize or attempt to monopolize these markets and has a dangerous probability of success.

335. HemoCue has threatened Stanbio's supplier of hemoglobin cuvettes and hemoglobin cuvette test meters and Stanbio's existing and prospective customers with the '457

patent. HemoCue is seeking to enforce the '457 patent. HemoCue has refused to grant a license to Stanbio under the '457 patent.

336. Stanbio's lost sales due to HemoCue's acts and the litigation costs incurred by Stanbio in the defense of HemoCue's bad faith enforcement of this invalid and unenforceable patent are an antitrust injury which flows from the antitrust wrong.

COUNT TWELVE
UNFAIR COMPETITION
AND TORTIOUS INTERFERENCE

337. HemoCue has engaged in unfair competition and has tortiously interfered with Stanbio's existing and prospective business relationships.

338. Specifically, without limitation, (1) HemoCue has intentionally engaged in wrongful conduct desired to interfere or disrupt with Stanbio's existing and prospective business relationships; (2) HemoCue's acts have caused Stanbio's economic relationships to be actually interfered with or disrupted; and (3) HemoCue's wrongful conduct, which was designed to interfere with or disrupt the relationships, has in fact caused injury to Stanbio.

339. Specifically, without limitation, HemoCue has made statements to customers and prospective customers to the effect that (1) HemoCue's '457 patent is valid and enforceable, (2) Stanbio's cuvettes infringe HemoCue's patent rights, (3) Stanbio's customers and prospective customers would infringe HemoCue's '457 patent, (4) Stanbio is an unreliable supplier due to its cuvettes infringing HemoCue's patent, (5) Stanbio's cuvettes are not approved or will not remain approved for use in HemoCue's test meter in high complexity laboratories; (5) Stanbio is unlawfully marketing Stanbio's cuvettes, (6) HemoCue's cuvettes are "patented," and (7) Stanbio's cuvettes are of a lesser quality or not as useful as HemoCue's cuvettes

COUNT THIRTEEN
LANHAM ACT VIOLATION – 15 U.S.C. §1125

340. HemoCue has violated the Lanham Act by making false and misleading statements in interstate commerce that misrepresent the nature, characteristics and qualities of Stanbio's hemoglobin cuvettes and HemoCue's hemoglobin cuvettes.

341. HemoCue's acts have and will continue to comprise a use of a false description of origin, false or misleading description of fact, or false or misleading representation of fact which is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person and, in commercial advertising or promotion, has misrepresented and is misrepresenting the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, all to Stanbio's injury and in violation of 15 U.S.C. § 1125.

342. Specifically, without limitation, HemoCue has made statements to customers and prospective customers to the effect that (1) HemoCue's '457 patent is valid and enforceable, (2) Stanbio's cuvettes infringe HemoCue's patent rights, (3) Stanbio's customers and prospective customers would infringe HemoCue's '457 patent, (4) Stanbio is an unreliable supplier due to its cuvettes infringing HemoCue's patent, (5) Stanbio's cuvettes are not approved or will not remain approved for use in HemoCue's test meter in high complexity laboratories; (5) Stanbio is unlawfully marketing Stanbio's cuvettes, (6) HemoCue's cuvettes are "patented," and (7) Stanbio's cuvettes are of a lesser quality or not as useful as HemoCue's cuvettes

COUNT FOURTEEN
STATE UNFAIR COMPETITION

343. HemoCue's acts have and will continue to comprise unfair competition against Stanbio under the laws of the State of Texas.

COUNT FIFTEEN
ROBINSON-PATMAN

344. HemoCue has violated the Robinson-Patman Act, i.e., 15 U.S.C. §§ 13, 14.

345. Specifically, without limitation, (1) HemoCue's sales of hemoglobin cuvettes and hemoglobin cuvette test meters meet the "in-commerce" requirements of the Robinson-Patman Act; (2) HemoCue is discriminating in price and terms between different purchasers of HemoCue's hemoglobin cuvettes and test meters, *i.e.* commodities of like grade and quality; (3) the effect of such discrimination is to substantially lessen competition or to tend to create a monopoly and (4) has caused Stanbio antitrust injury. HemoCue has market power in these commodities, intends its discrimination to maintain its market power and to cause Stanbio antitrust injury.

COUNT SIXTEEN
EXCEPTIONAL CASE

346. This is an exceptional case. 37 U.S.C. § 285.

V.
DAMAGES, ADDITIONAL RELIEF AND CONSOLIDATED ALLEGATIONS

347. Damages. HemoCue's acts have caused and will cause Stanbio actual damages. As a direct and proximate result of HemoCue's conduct, Stanbio has suffered and will continue to suffer actual damages and irreparable harm to its customer relationships. Stanbio seeks recovery of its damages under all available statutory and common law basis.

348. Punitive and Exemplary Damages On information and belief, HemoCue's above-described acts have been done knowingly, willfully and with reckless disregard for Stanbio's rights. Stanbio requests enhanced, punitive, and exemplary damages in an amount not less than three times Stanbio's actual damages pursuant to all available statutory and common law rights thereto.

349. Injunctive Relief. HemoCue's acts have and will cause Stanbio great and irreparable injury for which no remedy at law is adequate. Stanbio seeks permanent injunctive relief ordering HemoCue to cease the described unlawful acts and courses of action.

350. Attorneys Fees and Costs. Stanbio is entitled to recover its attorney's fees and costs under several statutory and common law basis. These include, without limitation, 35 U.S.C. § 285, 15 U.S.C. §§ 15, 16.

351. Consolidated Facts and Allegations. All of the facts asserted herein, whether by way of answer, affirmative defense or counterclaim, or otherwise are each asserted in support of each and every defense and claim herein and in Stanbio's Answer to HemoCue's Counterclaims. Further, this Complaint asserts unlawful tie ins, leveraging, and exclusive agreements by HemoCue between several of the asserted markets. Stanbio asserts such claims with respect to each combination of HemoCue's alleged markets. This Complaint is sufficiently lengthy and sufficiently apprises HemoCue of Stanbio's claims without repeating its allegations for each such activity.

VI.
PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Stanbio requests the following relief:

(a) Judgment that Stanbio's cuvettes do not infringe U.S. Patent No. 5,674,457.

(b) Judgment that U.S. Patent No. 5,674,457 is invalid and/or unenforceable.

(c) Judgment that Stanbio's sale and offering to sell its hemoglobin cuvette and hemoglobin cuvette test meter products is lawful.

(d) Judgment that HemoCue's courses of conduct set forth hereinabove are unlawful.

(e) Judgment that a permanent injunction issue enjoining HemoCue, its directors, officers, agents, servants, employees, attorneys, and all other persons acting in privity or in concert with them from:

(i) Representing that HemoCue's goods or services have qualities or characteristics which they do not have. This specifically includes, without limitation, that HemoCue's hemoglobin cuvettes are within the scope of a valid patent when they are not.

(ii) Representing that Stanbio's goods or services have qualities or characteristics which they do not have. This specifically includes, without limitation (1) representing that Stanbio's hemoglobin cuvette and test meter goods or services infringe a valid HemoCue patent, when they do not and (2) representing that Stanbio's hemoglobin cuvettes may not be lawfully used within HemoCue test meters in circumstances when they can be lawfully used.

(iii) Violating the antitrust laws of the United States. This includes, without limitation, 15 U.S.C. §1, 2, 13. This includes, without limitation (a) bundling or tying the sale of hemoglobin cuvettes and test meters, (b) discriminating in price between different customers, (c) entering into long-term supply agreements with customers, (d) entering into exclusive supply agreements with customers, (e) providing test meters at below cost to customers.

(iv) Continuing HemoCue's unlawful acts as complained of herein.

(f) Judgment that HemoCue pay Stanbio such damages, together with pre-judgment interest and post-judgment interest, as Stanbio has sustained as a consequence of HemoCue's wrongful acts.

(g) Judgment that HemoCue account to and pay to Stanbio all wrongful profits wrongfully obtained by HemoCue as a consequence of HemoCue's wrongful acts.

(h) Judgment that HemoCue pay Stanbio all applicable statutory, common law, treble, enhanced, punitive, and exemplary damages to Stanbio together with payment to Stanbio of an amount at least three times the amount of Stanbio's actual damages or HemoCue's wrongfully-obtained profits.

(i) Judgment that this is an exceptional case under 35 U.S.C. §285 and that HemoCue pay to Stanbio, Stanbio's expenses, attorneys' fees, and costs of this action, including, without limitation, attorney's fees, expenses, costs, and relief pursuant to 15 U.S.C. § 13 and 14, and 35 U.S.C. § 285, et. seq. and all applicable Texas and Federal statutes.

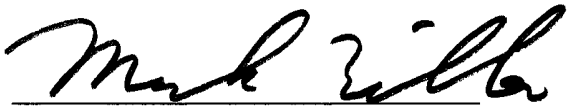
(j) Such other and further relief to which Stanbio is entitled.

JURY DEMAND

Stanbio respectfully requests trial by jury.

Respectfully submitted,

JACKSON WALKER L.L.P.
112 East Pecan Street, Suite 2100
San Antonio, Texas 78205-1521
(210)978-7700/(210)978-7790 (facsimile)

By: 
Mark H. Miller
State Bar No. 14099200
ATTORNEYS FOR STANBIO
LABORATORY, L.P.

CERTIFICATE OF MAILING

I hereby certify that this First Amended Compliant is being sent by U.S. Postage First Class, prepaid, on the 2 day of May, 2005, to:

Mr. Dean V. Fleming
300 Convent Street, Suite 2200
San Antonio, Texas 78205

Paul Krieger
Heather Fleniken
Fulbright & Jaworski LLP
1301 McKinney, Suite 5100
Houston, Texas 77010-3095

John K. Schwartz
Locke Liddell & Sapp LLP
100 Congress Ave., Suite 300
Austin, Texas 78701

Michael Lake
Ed Bishop
Factor & Lake ltd.
1327 W. Washington Blvd., Suite 5G/H
Chicago, Illinois 60607

MARK H. MILLER

EXHIBITS

Exhibit A - HemoCue's Analysis of "The Marketplace"

Exhibit B - U.S. Design Patent No. 337,388

Exhibit C - U.S. Trademark Registration No. 2,629,643

Exhibit D - HemoCue's Publication of a Prior Art HemoCue Cuvette

Exhibit E - Correspondence of January 10, 2005

Business Idea

We develop, produce and market in-vitro diagnostic products and services for the global professional point-of-care testing and home use markets.

HEMOCUE

EXHIBIT A.1

The Marketplace

Professional Centralized Testing

Hospitals
Reference labs

- Low growth! < 5 %
- Profitability a problem
- Response time a problem

Professional Decentralized Testing

Primary Health Care,
POLs, Occupational Health,
Blood banks, Diabetic Clinics,
Public Health, Hospital POCT,
Screening Programs

- Growth rate 8–12 %
- Health care is changing
- Few high quality players
- Ease of use and turn around time important
- Reimbursement driven market
- Development of new multi-analyzer

OTC/Home Health Care Patient Testing

Drug stores
Pharmacies
Mail-order houses

- Big market with strong growth 20 % +
- Distribution is complex
- Tough competition – big player
- High entry barriers
- Price/test key issue

Trend

HemoCue

HEMOCUE

EXHIBIT A. 2

Core Products

HemoCue B-Hemoglobin System

B-Hemoglobin Photometer (photometry instrument)
B-Hemoglobin Microcuvette

Intended Use
Determination of whole blood hemoglobin concentration in adults and neonates (measures neonatal blood).

Principal Applications
Screening, diagnosing, monitoring of anemia. Establishing O_2-carrying capacity in the acutely ill patient

HemoCue B-Glucose System

B-Glucose Analyzer (photometry instrument)
B-Glucose Microcuvette

Intended Use
Determination of whole blood glucose concentration in adults and neonates

Principal Applications
Screening, diagnosing, monitoring of diabetes. Establishing hypoglycemic state in neonates

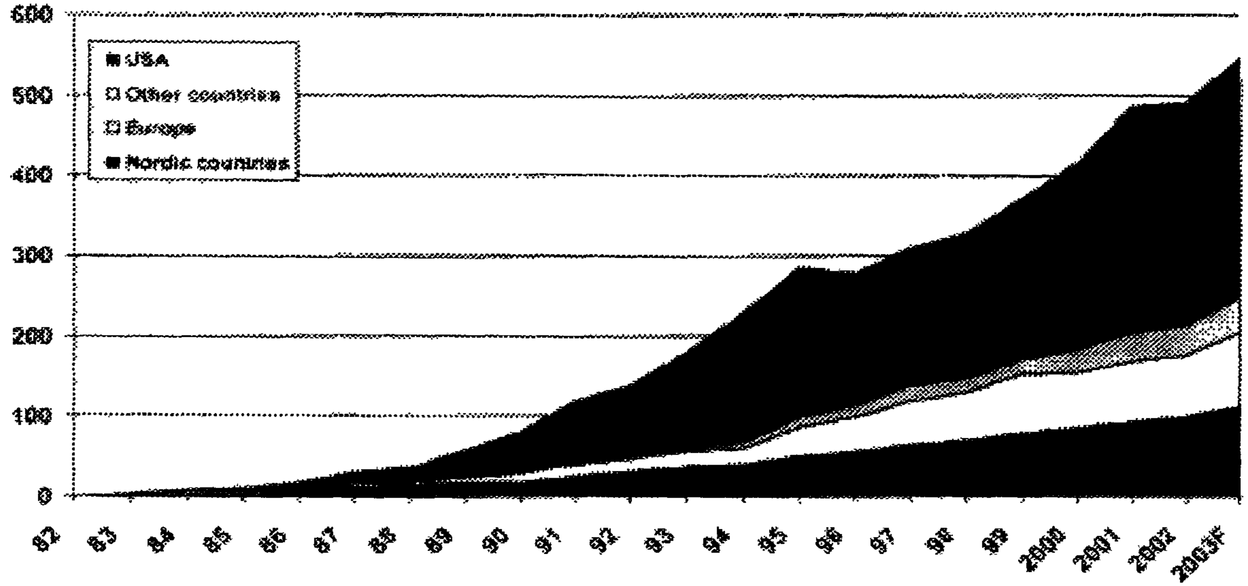
HEMOCUE

EXHIBIT A. 3

Customer Segments

EXHIBIT A.4

Sales 1982–2002 (MSEK)



Total MSEK	0,5	5	7	9	16	30	38	57	78	113	138	180	230	286	279	310	328	372	416	487	492	546F

HEMOCUE

EXHIBIT A.5

US00D337388S

United States Patent [19]

Nilsson et al.

[11] Patent Number: Des. 337,388

[45] Date of Patent: ** Jul. 13, 1993

[54] CUVETTE FOR AN OPTICAL ANALYSIS OF LIQUIDS

[75] Inventors: Sven-Erik Nilsson; Jan Lilja, both of Helsingborg, Sweden

[73] Assignee: Hemocue AB, Ängelholm, Sweden

[**] Term: 14 Years

[21] Appl. No.: 668,331

[22] Filed: Mar. 14, 1991

[30] Foreign Application Priority Data

Sep. 14, 1990 [SE] Sweden 9001958

[52] U.S. Cl. D24/224; D24/227

[58] Field of Search D24/224; 215/358, 365, 220/900, 23.2, 23.8; 356/246; 435/288; 422/65, 91, 99, 100; 600/360

[56] References Cited

U.S. PATENT DOCUMENTS

D. 261,816 4/1982 Beeler et al. ..... D24/227 X
D. 278,162 3/1985 Adam et al. D24/224
D. 286,728 5/1986 Allard D24/224
3,627,432 12/1971 Bergmann ..... 422/101 X
4,118,807 10/1978 Goldowsky et al. ..... 422/100 X
4,227,892 10/1980 Sandstedt et al. ..... D24/224 X

Primary Examiner—A. Hugh Ward
Assistant Examiner—J. Simmons
Attorney, Agent, or Firm—Kane, Dalsimer, Sullivan, Kurucz, Levy, Eisele & Richard

[57] CLAIM

The ornamental design for a cuvette for an optical analysis of liquids, as shown and described

DESCRIPTION

FIG. 1 is a side elevational view of a cuvette for an optical analysis of liquids showing our new design;
FIG. 2 is a top plan view thereof;
FIG. 3 is a bottom plan view thereof;
FIG. 4 is an end elevational view thereof;
FIG. 5 is an inverted perspective view thereof; and,
FIG. 6 is a perspective view thereof taken toward the same side as that shown in FIG. 5.

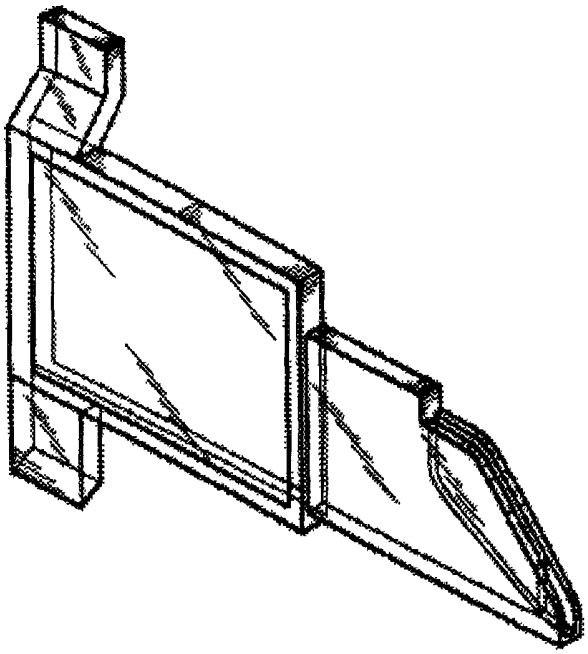


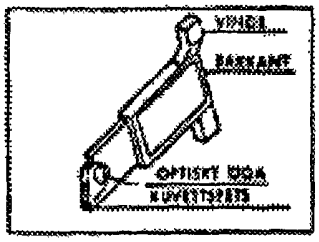
EXHIBIT B

Goods and Services	IC 009. US 021 023 026 036 038. G & S: COMPUTERS; ELECTRONIC APPARATUS FOR LABORATORY ANALYSIS, NAMELY, SPECTROPHOTOMETERS; AND SCIENTIFIC AND MEASURING APPARATUS AND INSTRUMENTS, NAMELY, PHOTOMETERS, LABORATORY GLASSWARE, BEAKERS, FLASKS, ELECTRONIC SENSORS FOR MEASURING LIQUIDS, BAR CODE READERS AND QUALITY CONTROL MATERIALS FOR CALIBRATION PURPOSES, NAMELY, CALIBRATORS FOR USE IN CALIBRATING AND VERIFYING THE ACCURACY OF PHOTOMETERS AND ELECTRONIC SENSORS USED FOR MEASURING LIQUIDS. FIRST USE: 19921217. FIRST USE IN COMMERCE: 19930900 IC 010. US 026 039 044. G & S: Medical apparatus and instruments for medical analysis, namely, cuvettes and microcuvettes. FIRST USE: 19921217. FIRST USE IN COMMERCE: 19930900
Mark Drawing Code	(2) DESIGN ONLY
Design Search Code	160904
Serial Number	75675649
Filing Date	April 7, 1999
Current Filing Basis	1A;44E
Original Filing Basis	1A
Published for Opposition	July 16, 2002
Registration Number	2629645
Registration Date	October 8, 2002
Owner	(REGISTRANT) HemoCue AB CORPORATION SWEDEN Kuvettgatan 1 SE-262 23 Angelholm SWEDEN
Attorney of Record	LAURENCE A. GREENBERG
Priority Date	December 30, 1998
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

EXHIBIT C

3.5 Utförande av hemoglobinbestämning

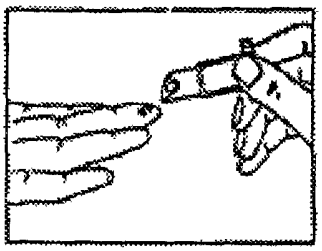
1 Ställ fotometerns strömbrytare i läge "ON". I avläsningsfönstret ses bokstäverna "Hb". Dra ut kuvettsläden till sitt yttre läge. När "Hb" i avläsningsfönstret ersatts av tre blinkande streck, är fotometern klar för mätning.



2 Tag ut erforderligt antal kuvetter ur burken och sätt omedelbart på locket. OBS! Avlägsna ej torkmedlet. Utför kapillärprovtagning på vedertaget sätt (första bloddroppen avtorkas), resp. tag fram det venblod som skall analyseras.

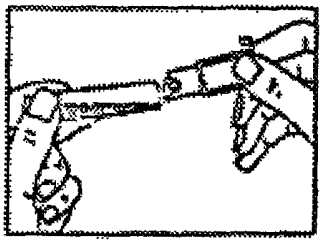
3 Fyllning av kuvetten

Håll kuvetten i den bakre vingförsedda delen.



Kapillärblod

För kuvettspetsen mot bloddroppen. Se till att bloddroppen är tillräckligt stor för att fylla hela kuvetten *på en gång*.
Undvik blod på kuvettens utsida.



Venblod (väl blandat!)

Luta röret med venblod och för kuvettspetsen mot blodytan så att hela kuvettens fylls *på en gång*.
Undvik att få blod på kuvettens utsida.
Kuvetten skall vid provtagningen fyllas helt. Inga luftblåsor får finnas i det optiska ögat. Mindre luftblåsor längs kanten påverkar ej resultatet.

EXHIBIT D

ATTORNEYS & COUNSELORS
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JACKSON WALKER L.L.P.

Mark H. Miller
(210) 978-7751
mmiller@jw.com

January 10, 2005

Mr. Paul E. Krieger
Fulbright & Jaworski L.L.P.
1301 McKinney, Suite 5100
Houston, Texas 77010-3095

Re: *HemoCue AB; HemoCue, Inc. v. Stanbio Laboratory, L.P.; EKF – Diagnostic GmbH*, Cause No. 04CV1378BEN(AJG), in the United States District Court, Southern District of California
Our File No. 124716.00002

Dear Mr. Krieger:

You will recall that, responsive to your phone request upon your receiving service of this suit, I promptly provided you with samples of the subject EKF cuvettes in my letter to you of December 4, 2003, *i.e.* over a year ago.

My October 22, 2004 letter to you (1) renewed my July 2004 request for a copy of the report that HemoCue relies on for its assertion that the EKF cuvette infringes HemoCue's '457 patent and (2) renewed my request that HemoCue forward a few dozen of the cuvettes that HemoCue was using commercially on or before April 26, 1995, i.e. one year prior to the application leading to HemoCue's '457 patent. Without these two items, it is impossible for Stanbio to properly evaluate HemoCue's patent infringement allegation.

To put in print what you already know, (1) if and when Stanbio needs additional time to review the report that HemoCue relies on and which HemoCue will not provide to Stanbio, or to test HemoCue's pre-April 26, 1995 cuvettes, or to act on information derived from those or (2) if and when Stanbio needs to rebut an accusation of willful infringement, I will submit a copy of this letter. I will explain to the Court and jury that I have been seeking these two noncontroversial items of information from HemoCue since July, 2004 and that HemoCue has not supplied them.

Please send the report and cuvettes.

Sincerely,

Mark H. Miller

Enclosures
cc: Jody Factor

Austin
Dallas
Fort Worth
Houston
Richardson
San Angelo
San Antonio

3754870v.1 124716/00001

EXHIBIT E